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No. 02-

IN THE

Supreme Court of the United States

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC.,
Petitioner,

v.

BIOMEDICAL SYSTEMS CORPORATION,
Respondent.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether a manufacturer who seeks expedited marketing clearance for a medical device from the Food and Drug Administration ("FDA") – and thereby avoids extensive FDA safety and effectiveness review – violates federal law by submitting a false application to the FDA that fails to disclose the true intended use of the device and instead discloses an intended use that the manufacturer has no intention of promoting, and for which no physician will prescribe the device.

PARTIES TO THE PROCEEDING

The only parties to the proceeding are the Petitioner and Respondent listed in the caption. In the proceedings below, petitioner was identified as GE Marquette Medical Systems, Inc.

Pursuant to Rule 29.6 of the Rules of this Court, Petitioner states that it is a wholly owned subsidiary of General Electric Company. Petitioner further states that no publicly traded company owns ten percent or more of the stock of General Electric.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner GE Medical Systems Information Technologies, Inc. ("GE") respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eighth Circuit in this case.

OPINIONS BELOW

The opinion of the Eighth Circuit was entered on April 23, 2002, is reported at 287 F.3d 707, and is reproduced in the appendix hereto ("App.") at 1a-3a. The order denying GE's Petition for Rehearing and Rehearing en Banc, App. 7a, was entered on July 19, 2002, and is not reported. The final judgment of the United States District Court for the Eastern District of Missouri was entered on April 10, 2001, and is not reported. It is reproduced in the appendix at 4a-5a.

JURISDICTION

The Eighth Circuit entered its judgment in this case on April 23, 2002, App. 1a-3a, and denied the Petition for Rehearing en Banc on July 19, 2002. App. 7a. The jurisdiction of the Eighth Circuit was based on 28 U.S.C. § 1332. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The statutes at issue in this case are 21 U.S.C. §§ 360(k), 360c(f)(1), (i)(1)(A), and 360e(a)-(b)(1), and are reproduced at App. 8a-11a. The regulations at issue in this case are 21 C.F.R. §§ 801.4 and 807.87(e)-(f), and are reproduced at App. 12a-13a.

STATEMENT OF THE CASE

The Eighth Circuit's extraordinary decision in this case poses a significant threat to the integrity of the regulatory process used to grant expedited marketing authority for new medical devices. In that expedited process, the Food and Drug Administration ("FDA") does not conduct a full-blown review of the safety and effectiveness of a new device, but instead determines only whether the new device is "substantially equivalent" to certain devices already lawfully on the market. To determine substantial equivalence, the FDA is required to examine whether the new device has the same "intended use" as the device already on the market.

In the decision below, the Eighth Circuit held that it does not violate federal law for a manufacturer to misrepresent the intended use of a medical device for which the manufacturer seeks expedited marketing clearance. That ruling undermines a principal safeguard of the expedited clearance process, threatens patient health and conflicts with the Third Circuit's contrary conclusion in *In re Orthopedic Bone Screw Products Liability Litigation*, 159 F.3d 817 (3d Cir. 1998), *rev'd on other grounds*, *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2000), as well as with the FDA's authoritative interpretation of its governing regulations. Indeed, the FDA has explained that a manufacturer must disclose the actual use for which the manufacturer intends to market and distribute a medical device, and cannot rely on an intended use that is merely "a pretext calculated to clear the device for distribution for other uses." Brief of *Amicus* Food and Drug Administration at 15, *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2000) (No. 98-1768) ("FDA *Amicus* Br.").

The Eighth Circuit's decision in this case raises questions of exceptional importance. It affirmatively countenances deceit of government regulators and the gaming of a regulatory system designed to ensure the safety of those who

use medical devices. At a time of heightened public and congressional concern over corporate malfeasance, the need to promote honest and candid dealings with regulators charged with protecting public health and safety could not be more compelling. Yet the decision below punishes petitioner for following the directions of FDA regulators and for refusing to submit a pretextual request for expedited marketing clearance. As a result, the decision can only encourage less scrupulous entities to file misleading submissions with the agency. And, even if the FDA succeeds in detecting misrepresentations, its ability to punish dishonest manufacturers will be undermined by the Eighth Circuit's decision, which manufacturers can cite as authority for the proposition that failure to disclose the sole intended use of a medical device is entirely permissible. This Court should grant the petition and review the lower court's plainly erroneous decision.

A. Statutory and Regulatory Background

Congress first provided the FDA with authority to regulate the marketing and distribution of medical devices in 1976. By the early 1970s, Congress recognized that many medical devices available to the public ranged from completely ineffective to extremely dangerous. In response to mounting consumer and regulatory concern, Congress amended the Federal Food, Drug, and Cosmetic Act ("FDCA"), ch. 675, 52 Stat. 1040 (1938), and enacted the Medical Device Amendments of 1976 ("MDA" or "Act"), Pub. L. No. 94-295, 90 Stat. 539 (both statutes codified as amended at 21 U.S.C. § 301 *et seq.*).

The MDA categorizes medical devices into three separate classes based upon the risk they pose to the public. Class I devices are "those that present no unreasonable risk of illness or injury and therefore require only general manufacturing controls." *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2000); see also 21 U.S.C. § 360c(a)(1)(A). Class II devices are "those possessing a greater potential

dangerousness and thus warranting more stringent controls." *Buckman*, 531 U.S. at 344. Class III devices are those that either present "a potential unreasonable risk of illness or injury," or those which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C). Class III devices must undergo a time-consuming, premarket approval ("PMA") process before they may be marketed to the general public. All devices that were not in commercial distribution prior to 1976 are automatically classified as Class III devices. *Id.* § 360c(f)(1).

Given the significant public health and safety concerns associated with the introduction of new medical devices, the FDA's regulatory scrutiny is intensive. Thus, to obtain premarket approval, manufacturers of new devices are required to submit information to the FDA that provides "reasonable assurance" that the device is both safe and effective. *Id.* § 360e(d)(2). Although this PMA procedure is costly and time-consuming, requiring the submission of voluminous information that details the safety and effectiveness of the device, it is vital to ensuring that the public's health is protected. This is why the FDA spends approximately 1,200 hours reviewing and processing each PMA submission. *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 477 (1996) (citing *Hearings before the Subcomm. on Health and the Environment of the House Comm. on Energy & Commerce*, 100th Cong. 384 (1987)).

B. The 510(k) Exception

The MDA provided several important exceptions to the PMA process. First, it allowed "pre-amendment" Class III devices – *i.e.*, Class III devices that were on the market prior to passage of the MDA – to remain on the market until the FDA completes a rulemaking requiring the submission of a PMA for each such device. 21 U.S.C. § 360e(b)(1)(A). Second, to avoid giving monopolies to such grand-fathered

devices, *Buckman*, 531 U.S. at 345, the MDA allows manufacturers to distribute new devices that are shown to be "substantially equivalent" to a pre-amendment Class III device. 21 U.S.C. § 360e(b)(1)(B).[1] Third, the MDA allows manufacturers to distribute new devices that are shown to be "substantially equivalent" to any devices, whether pre- or post-amendment, that are classified as Class I or Class II devices. *Id.* § 360c(f)(1).

Manufacturers seeking marketing authorization for new devices under the last two exceptions must use what is referred to as the 510(k) notification process.[2] This fast-track process involves a limited form of agency review that focuses only on the question of whether the new device is "substantially equivalent" to a predicate device. Under the statute, a device is "substantially equivalent" if it "has the *same intended use* as the predicate device" and if the FDA finds either that it has the "same technological characteristics as the predicate device," or is at least "as safe and effective as a legally marketed device." *Id.* § 360c(i)(1) (emphasis added). To establish "substantial equivalence," a manufacturer must submit, among other things, "[p]roposed labels, labeling, and advertisements sufficient to describe the device, *its intended use*, and the directions for its use," and "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement." 21 C.F.R. § 807.87(e), (f) (emphasis added). The statute affords the FDA 90 days to determine whether the device is "substantially equivalent." 21 U.S.C. § 360(k).

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[1] Once the FDA completes the rulemaking requiring a PMA for the pre-amendment Class III device, any "substantially equivalent" post-amendment devices must likewise submit a PMA. *See* 21 U.S.C. § 360e(b)(1)(B).

[2] Section 510(k) of the MDA is codified at 21 U.S.C. § 360(k). Pub. L. No. 94-295, sec. 4(k), § 510(k), 90 Stat. at 580.

While a standard PMA review takes over 1,200 hours for the agency to complete, a 510(k) notification review is completed in an average of about 20 hours. *Medtronic*, 518 U.S. at 478-79. In sharp contrast to a PMA, the 510(k) notification "'requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly.'" *Id.* at 479 (quoting Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 516 (1988)). Not surprisingly, device manufacturers find the 510(k) process preferable to the more onerous PMA process.[3]

Both processes, however, are similar in that thorough disclosures and accurate information are critical to the FDA's ability to protect health and safety. The manufacturer's representations concerning the "intended use" of a device, therefore, play a crucial role in ensuring that the expedited 510(k) process does not allow unsafe devices to reach the public. In a 510(k) proceeding, the FDA does not determine that either the new device or the predicate device is safe. See *Medtronic*,, 518 U.S. at 479. Instead, Congress reasonably concluded that if a device is already in commercial use, permitting a substantially equivalent device to reach the market was unlikely to harm the public. But, because a medical device that is safe for one use may be unsafe for another, Congress directed the FDA, when making a "substantial equivalence" determination, to examine whether the new device "has the same intended use as the predicate device." 21 U.S.C. § 360c(i)(1).

Under FDA regulations, "intended use" must be determined based on the "objective intent of the persons legally responsible for the labeling of [the] device[]." 21 C.F.R.

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[3] As of 1990, over 80% of new Class III devices were being introduced to the market through the 510(k) process. H.R. Rep. No. 101-808, at 14 (1990); *Medtronic*, 518 U.S. at 479.

§ 801.4. A device's labeling is thus relevant to, but not dispositive in, determining the use the manufacturer intends for the device. Other relevant evidence includes "advertising matter," a manufacturer's "oral or written statements," and the manufacturer's "knowledge" that the device is "offered and used for a purpose for which it is neither labeled nor advertised," or that it "is to be used" for purposes other than those for which the manufacturer has offered it. *Id.* Accordingly, when the FDA "seeks from an applicant a statement of a device's intended use, it is not simply asking for the use that will appear on the labeling." FDA *Amicus* Br. at 14-15.

The FDA recognizes that physicians often use medical devices for purposes that are not identified in the devices' labeling, and it does not require manufacturers seeking 510(k) clearance to disclose every possible "off-label" use to which the device might be put. The FDA has stated, however, that:

> when, at the time of the application, a manufacturer plans to promote and distribute a device *exclusively* for one use, it must disclose to FDA that intended use. A statement to FDA that the device has a different intended use would be false and misleading. The intended use stated in the premarket notification must be a bona fide use; *it cannot be a pretext calculated to clear the device for distribution for other uses.*

Id. at 15 (emphases added).[4]

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[4] Accurate disclosure of intended use took on even greater importance in light of the FDA Modernization Act of 1997 ("FDAMA"). That Act provides that, for a period of five years, when the FDA makes substantial equivalence determinations, determinations of intended use "shall be based upon the proposed labeling." 21 U.S.C. § 360c(i)(1)(E)(iv). The FDAMA thus makes it imperative that a manufacturer disclose the actual intended uses of its device: if the intended use on the label is merely a pretext, a determination that this pretextual use is the same that of the predicate device fails to provide any assurance of safety and effectiveness – precisely what substantial equivalence determinations are intended to

C. FDA Classification of Home Uterine Activity Monitors

This case involves a medical device known as a home uterine activity monitor ("HUAM"). Uterine activity monitors were in commercial distribution prior to enactment of the MDA and, in 1980, the FDA listed these devices as Class II devices. Obstetrical and Gynecological Devices; Classification of External Uterine Contraction Monitors and Accessories, 45 Fed. Reg. 12,696, 12,696 (Feb. 26, 1980) (to be codified at 21 C.F.R. § 884.2720). Accordingly, substantially equivalent new products were qualified to apply for clearance under § 510(k).

During the early 1980s, the FDA granted several 510(k) clearances for uterine activity monitors that were intended for use by women at full-term. Physicians, however, soon began to prescribe the devices for a new use: early detection of pre-term labor in high-risk patients at home. Obstetrics and Gynecology Devices; Reclassification of Home Uterine Activity Monitor, 64 Fed. Reg. 41,435, 41,436 (July 30, 1999) (notice of panel recommendation). Physicians found the HUAM to be helpful in detecting pre-term labor, especially because the woman did not need to be present in a clinical setting to have her contractions monitored.

This new use of HUAMs, however, posed a new set of risks. The most troublesome was an increased risk of a false positive, indicating pre-term labor when none was present. A false diagnosis of this type often resulted in unnecessary hospitalization, potentially risky drug treatment, and deleterious patient stress. *Id.* at 41,437.

As these problems were coming to light during the 1980s and early 1990s, several manufacturers submitted 510(k)

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provide. *See* FDA *Amicus* Br. at 16 n.2 (FDAMA "underscores why a manufacturer seeking Section 510(k) clearance for a device must disclose all intended uses of the device, and not merely those set forth in [the] proposed labeling").

notifications for HUAMs stating that the device was intended for full-term monitoring. After granting several of these applications, the FDA became increasingly concerned that the monitors were in fact being marketed for the riskier use of pre-term monitoring. Appendix of Defendant-Appellant at 341-43, *Biomedical Sys. Corp.* v. *GE Marquette Med. Sys., Inc.*, 287 F.3d 707 (8th Cir. 2002) (No. 01-3076) ("Appellant App."). Ultimately, it determined that use of HUAMs for the early detection of pre-term labor constituted a new intended use, and that, for this new use, "the HUAM was not substantially equivalent to any . . . device . . . that had been classified into class I or class II for the early detection of [pre-term labor]." 64 Fed. Reg. at 41,436. The FDA changed the classification of the HUAM from a Class II device to a Class III device, and advised manufacturers that the device "*could not be placed in commercial distribution for early detection of [pre-term labor]* in high risk patients *unless it was reclassified . . . or subject to an approved PMA*." *Id.* (emphasis added).

By 1992, the FDA's change in regulatory policy was complete. The agency granted no 510(k) clearances for a HUAM claimed to be intended for term use after 1992. Appellant App. 344. HUAM manufacturers seeking to market such devices had only two options: (1) submit to the thorough PMA process, or (2) petition the FDA for reclassification of the device. Indeed, in 1993, an FDA advisory panel concluded that the HUAM was "a good candidate for reclassification" and invited manufacturers "to petition FDA for a change in classification of the devices." 64 Fed. Reg. at 41,437.

D. The Underlying Dispute

Respondent Biomedical Services ("Biomedical") provides HUAMs to women with high-risk pregnancies who are at risk of pre-term labor. It offers daily or weekly "Pre-term Labor Management" services, and its promotional materials focus on the benefits of HUAMs for women who are at risk of pre-

term labor. Women who are at term, and by definition no longer at risk of pre-term labor, have no need for Biomedical's products or services.

In the early 1990s, Biomedical developed the technology for a new HUAM. In April 1996, it began negotiating with GE's predecessor in interest, Corometrics, a company which had the capacity to manufacture the HUAM and a sizeable sales force for distributing and marketing it. During this initial meeting, Corometrics informed Biomedical's owner and founder, Ray Barrett, that "you cannot do a 510(k)" for the new monitor. Appellant App. 35. One month later, Biomedical's own regulatory specialist likewise confirmed that, before obtaining FDA clearance for the HUAM, the FDA would need to "reclassify the device from its current class III to a class I or II" to make "it easier to obtain market clearance for our device and desire[d] use." Appellant App. 452. "We should pursue this [reclassification] direction no matter what else we do. . . . [O]nce a reclassification occurs, a 510(k) will need to be filed." *Id.*

On January 28, 1997, the parties executed a Technology Transfer Agreement ("Agreement") in which Corometrics agreed to "obtain clearance for a 510(k) application," *id.* at 455 (¶ 1), and to ensure that "the Monitor has qualified for a 510(k) application." *Id.* at 456 (¶ 3). Corometrics concluded that, in order to comply with this obligation, it simultaneously had to petition the FDA for reclassification of a pre-term monitor as a Class II device, and file a 510(k) that would be granted immediately upon the HUAM's re-classification. In fact, FDA officials recommended this precise course of action. *Id.* at 335.

After Corometrics filed the reclassification petition, however, groups such as the National Women's Health Network and the American College of Obstetricians and Gynecologists strenuously opposed it on health and safety grounds. This intense opposition substantially delayed the reclassification process. *Id.* at 673. Nevertheless, for two

years after signing the Agreement, Biomedical stood by its support of Corometrics' decision. After GE acquired Corometrics, however, Biomedical filed suit, alleging that, by failing to file a 510(k) notification for *term* use, GE's predecessor had breached the Agreement.

E. This Litigation

In the trial court, Biomedical claimed that GE was contractually obligated to file a 510(k) submission claiming that the device was intended for *term* use, even though the parties never intended to market the device for that use and instead intended to market it solely for pre-term monitoring. GE argued that the contract could not have the meaning Biomedical ascribed to it because, so construed, the contract would have required GE to file an application misrepresenting the HUAM's intended use, in violation of FDA regulations and federal criminal law. The district court ruled, however, that the meaning of the contract was ambiguous, and that its meaning was a question of fact for the jury. *Biomedical Sys. Corp.* v. *GE Marquette Med. Sys., Inc.*, No. 4:99-CV-1590-CAS, slip op. at 6 (E.D. Mo. Mar. 1, 2001) (order denying motions to dismiss and for summary judgment).

The evidence at trial confirmed that the sole intended use of the monitor was for pre-term pregnant women. Biomedical promotes its monitoring services as appropriate for home use by pre-term pregnant women. The sole use identified in Biomedical's complaint was pre-term monitoring, and the damage formula Biomedical presented at trial relied entirely on alleged "lost profits" from pre-term use of the monitor. Biomedical's own medical expert testified that he had never used a HUAM for purposes of detecting contractions in a full-term patient, and GE's expert testified that he could not imagine why anyone would now prescribe the device for full

term use. Biomedical offered no evidence that the device was in fact ever prescribed for term use.[5]

The district court refused to consider the fact that Biomedical's interpretation would have resulted in an agreement that was illegal, and thus unenforceable, under the FDA's regulation. Instead, the judge allowed Biomedical to argue that the contract required GE to file a pretextual 510(k) for term use, and he barred GE from offering rebuttal evidence regarding the FDCA violations that would result from such a reading.[6] As a result, the jury returned a verdict in favor of Biomedical for breach of contract and assessed $75 million in damages against GE.

F. Decision of the Eighth Circuit

On appeal, GE again argued that, as Biomedical construed it, the contract was unenforceable because it would require the filing of a false and misleading application. Biomedical's response made unmistakably clear that it sought to hold GE liable for failing to file a purely pretextual 510(k) submission. Biomedical claimed that GE should have "fil[ed] a 510(k) for term use," and then "*covered its flanks*" with labels stating that the device was not approved for pre-term monitoring. Br. of Appellee at 41, 43 (emphasis added). Biomedical argued that, because the FDAMA restricts the FDA's determination of "intended use" to the use disclosed in the proposed label, labels stating that the device was approved only for term use would have completely shielded GE from any charge of

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[5] A Biomedical nurse stated that 10% of *pre-term* patients continue to wear the device after they reach full term. Trial Tr. XII-B-54-55. In such circumstances, of course, the device is neither prescribed nor intended for full term use.

[6] In response to GE's repeated attempts to introduce evidence that Biomedical's proposed interpretation of the contract would require GE to commit a fraud on the FDA, the trial judge said: "Legal, illegal, forget it. Right, wrong, forget it.... Whether it was right, wrong, good, bad, screw all that." Appellant App. 111-12.

falsity or illegality, *id.* at 31 – even though the HUAM was indisputably *not* intended for term use and no physician would ever prescribe it for such use. According to Biomedical, FDA regulations that require applicants to base "intended use" on knowledge that a device will be offered and used for purposes that do not appear on the label are simply irrelevant in light of the FDAMA. *Id.* The FDA's contrary "analysis of 'intended use' in the *Buckman amicus* brief," Biomedical claimed, "is mistaken." *Id.* at 41.

The Eighth Circuit accepted these arguments in a brief, per curiam opinion. According to the lower court, "the contract unambiguously required GE to apply for 510(k) clearance and *did not require GE to violate federal law*." App. 2a-3a (emphasis added). The Eighth Circuit's key holding that the contract, as construed by Biomedical, was not illegal allowed the court to affirm the $75 million damages verdict that the jury assessed against GE for failing to file a pretextual 510(k) notification. The court denied the petition for rehearing and rehearing en banc without opinion on July 19, 2002.

REASONS FOR GRANTING THE PETITION

The decision below conflicts with the Third Circuit's holding in *In re Orthopedic Bone Screw Products Liability Litigation*, 159 F.3d 817 (3d Cir. 1998), and with the FDA's authoritative interpretation of the regulations that govern the 510(k) application process. Indeed, both the Third Circuit and the FDA, in its Buckman *Amicus* Brief, explicitly condemned the very actions that the lower court approved in this case. Permitting manufacturers to evade meaningful regulation by misrepresenting the intended use of a medical device will greatly hamper the FDA's ability to do its job. Indeed, a holding that does such violence to the integrity of a regulatory scheme intended to protect public health and safety is of exceptional importance.

The significance of the erroneous ruling below is not diminished by the Eighth Circuit's cursory effort to explain the basis of its judgment. The issue of whether a manufacturer can submit a 510(k) notification that fails to disclose the actual intended use of a medical device was squarely presented and fully aired below. Petitioner cited the FDA's regulations, and the agency's interpretation of those regulations, and argued at length that the regulations rendered respondent's interpretation of the contract illegal. Respondent claimed that the regulations were irrelevant under the FDAMA, and dismissed the FDA's contrary view as "mistaken." The Eighth Circuit expressly addressed the issue, holding that it would "not . . . violate federal law" for GE to file a 510(k) notification that the FDA, and the Third Circuit, would deem false and misleading. The Eighth Circuit's holding is binding precedent, and creates a conflict both among the circuits and between the Eighth Circuit and the federal agency charged with administration of the federal statutes at issue.

The import of the Eighth Circuit's holding, moreover, will not be lost on medical device manufacturers. Manufacturers are sophisticated entities, subject to an elaborate and complex regulatory regime, with obviously strong incentives to use the expedited and far less expensive 510(k) process to bring new products to market. A $75 million verdict against a fellow manufacturer will not escape notice within this community, particularly a verdict predicated on the theory that FDAMA overrides the FDA's intended use regulations, and permits a manufacturer to label a device for a use that is not actually intended.

The Eighth Circuit's erroneous decision thus creates a serious risk that other manufacturers will embrace respondent's view of the regulatory scheme, and will submit 510(k) notifications that, under the FDA's contrary – and indisputably correct – view of the law, are false and misleading. The FDA, in turn, will be forced to devote

limited resources to detecting such 510(k) submissions. And even if it succeeds in identifying such submissions, the manufacturers can cite the Eighth Circuit's ruling to show that their conduct is permissible.

I. THE RULING BELOW CONFLICTS WITH A DECISION OF THE THIRD CIRCUIT.

In *In re Orthopedic Bone Screw Products Liability Litigation*, 159 F.3d 817 (3d Cir. 1998), the Third Circuit held that an applicant for 510(k) clearance cannot "represent[] that it intend[s] to market its device for one use when, in fact, it intend[s] at the time of the application to market that device solely for another, more hazardous use." *Id.* at 828. That ruling remains good law in the Third Circuit. The Eighth Circuit's ruling in this case simply cannot be reconciled with the Third Circuit's ruling.

In *Orthopedic Bone Screw*, a manufacturer twice sought FDA clearance for a bone screw for use in spinal surgery. After the FDA denied both applications on the ground that the device was not substantially equivalent to a pre-existing device, the manufacturer filed a third notification stating that the device was intended for use in arm and leg surgery. Based upon this "revised" statement of intended use, the FDA granted 510(k) approval. The manufacturer thereafter marketed the bone screw to physicians for spinal surgery. The bone screws proved to be unsafe for use in spinal surgery, and the many individuals injured by that use sued the manufacturer under state law, alleging fraud-on-the-FDA.

The manufacturer argued that the claims against it had to be dismissed because, as a matter of federal law, a statement of intended use by a 510(k) applicant is not a representation of actual marketing intentions upon which the FDA can rely in granting market clearance, but rather is a description of the authority the manufacturer seeks. *Id.* at 826-27. Like respondent, the manufacturer argued that "the sole interest of the FDA in the applicant's intended use is to enable [the

FDA] to limit the authority granted to that which is sought and considered by the agency." *Id.* at 827. Any concerns about "off-label" use of a device, it argued, can be addressed through labeling restrictions. *Id.*

The Third Circuit emphatically disagreed, stating that:

> [t]o the extent [the manufacturer's] argument is an assertion of law, we find no basis for it in the statute, in the regulations, or in any of the authorities cited . . . . Because the degree of risk presented by any device is a function of the use to which it is put, the intended use is thus a central focus in the FDA review. *Indeed, there is nothing more material to its determination of whether to grant access to the market.*

Id. at 828 (emphasis added).

The court recognized "that a manufacturer unable lawfully to secure a § 510(k) clearance for one purpose may legally be entitled to a § 510(k) clearance for the same device when put to a different purpose." *Id.* But, in words fully applicable to this case, the Third Circuit held that a manufacturer cannot secure 510(k) clearance "by representing that it intend[s] to market its device for one use when, in fact, it intend[s] at the time of the application to market that device solely for another, more hazardous use." *Id.* Such a representation, the Third Circuit held, was "fundamentally at odds with the [FDA's] gatekeeping assignment," and struck at the heart of the regulatory regime, because "[a] device that presents no risk of injury when employed for one purpose may present great risk of injury when employed for another." *Id.*

It is thus clear that, under the law of the Third Circuit, GE could *not* have "fil[ed] a 510(k) for term use," and then "covered its flanks" with labels stating that the device was not approved for pre-term monitoring. Br. of Appellee at 41, 43. The Third Circuit would rule – correctly – that a contract requiring such conduct is illegal and unenforceable. The

Eighth Circuit, however, squarely held that such a contract "did not require GE to violate federal law." App. 2a-3a.

Although this Court reversed the Third Circuit's conclusion that state law fraud-on-the-agency claims are not preempted, *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2000), the Court did not disagree with, or cast any doubt upon, the Third Circuit's holding that a manufacturer cannot represent that it intends to market a device for one use when it intends at the time of the application to market that device solely for another use. Rather, this Court reasoned that it was the FDA's "responsibility to police fraud," and that allowing juries to punish fraud on the agency under state law would inevitably result in conflicts with the FDA's exercise of that responsibility. *Id.* at 350. Thus, the Third Circuit's ruling that a manufacturer must disclose its actual marketing intentions for a device, and that a failure to do so was "fundamentally at odds" with the 510(k) regime, remains good law, and conflicts with the central basis for the holding of the Eighth Circuit here. Indeed, the FDA, which urged preemption of state tort claims, fully *agreed* with the Third Circuit's ruling in this regard. See *infra*, § II.

II. THE EIGHTH CIRCUIT'S DECISION CONFLICTS WITH THE FDA'S AUTHORITATIVE INTERPRETATION OF THE REGULATIONS GOVERNING THE 510(K) PROCESS.

In the *amicus* brief filed in *Buckman*, the FDA expressly rejected the very theories that respondent advanced – and the Eighth Circuit accepted – in this case. Because an agency's interpretation of its own regulations is entitled to the highest degree of judicial deference, *Auer* v. *Robbins*, 519 U.S. 452, 461 (1997) (applying principle to views set forth in an *amicus* brief), the Eighth Circuit's failure to follow the views of the agency charged with administering the federal statutes at issue in this case provides an additional compelling reason for review by this Court.

The petitioner in *Buckman*, like respondent here, argued that, "under federal law, 'intended use' refers to the use set forth in the labeling," not the "manufacturer's subjectively desired off-label uses." FDA *Amicus* Br. at 14. The FDA explained that this claim "misreads . . . the applicable federal standards." *Id.* "[W]hen FDA seeks from an applicant a statement of a device's intended use, it is *not simply asking for the use that will appear on the labeling*." *Id.* at 14-15 (emphasis added). Rather, federal law requires a manufacturer to disclose "the intended use that will be revealed by all of the manufacturer's 'expressions' and 'the circumstances surrounding' the device's 'distribution.'" *Id.* at 15 (quoting 21 C.F.R. § 804.1). These "surrounding circumstances" and "expressions" include not only the proposed labeling, but also (1) "'advertising matter,'" (2) a manufacturer's "'oral or written statements,'" (3) the manufacturer's "'knowledge'" that a product is "'offered and used for a purpose for which it is neither labeled nor advertised,'" and (4) the manufacturer's knowledge of facts that would give him "'notice'" that a product "'is to be used'" for purposes other than those for which the manufacturer offered it. *Id.* at 14; see also *United States* v. *Bowen*, 172 F.3d 682 (9th Cir. 1999) (intended use "'may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.'").

Embracing the views of the Third Circuit, the FDA emphasized that when:

> a manufacturer plans to promote and distribute a device exclusively for one use, it *must* disclose to FDA that intended use. A statement to FDA that the device has a different intended use would be *false and misleading*. The intended use stated in the [510(k)] must be a bona fide use; it cannot be a pretext calculated to clear the device for distribution for other uses.

FDA *Amicus* Br. at 15 (emphases added).

The FDA also flatly rejected the theory that the FDAMA rendered the agency's "intended use" regulations irrelevant. This Act, the FDA explained, "does not relieve manufacturers of their obligation . . . to truthfully inform FDA of a device's 'intended use' as that term is defined in FDA's 'intended use' regulation, 21 C.F.R. 801.4." *Id.* at 15 n.2. The agency noted that other provisions of the FDAMA authorized the FDA to require statements on labels if it determines that "there is a reasonable likelihood that the device will be used for an intended use *not identified in the proposed labeling*." 21 U.S.C. § 360c(i)(1)(E)(i)(I) (emphasis added). This authority, the FDA explained, "underscores why a manufacturer . . . must disclose all intended uses of the device, not merely those set forth in whatever proposed labeling the manufacturer chooses to submit in the Section 510(k) clearance process." FDA *Amicus* Br. at 16 n.2.

The FDA's authoritative interprepretation of the governing regulations makes clear that GE could not have filed a 510(k) notification for term use and then "covered its flanks" with labeling disclaimers when the parties had no intention of marketing the device for term monitoring and knew that no physician would ever prescribe it for such use. Contrary to respondent's view, the FDA's interpretation is not "mistaken," Br. of Appellee at 41, but entitled to great deference. *Auer*, 519 U.S. at 461. Indeed, its position that applicants must file truthful applications is unassailable, as such information is indispensable to the proper functioning of the regulatory scheme governing the marketing of medical devices. Because the Eighth Circuit upheld a contract interpretation that required conduct violative of the FDA's 510(k) regulations, this Court should grant the petition and reverse the lower court's clear error.

III. THE EIGHTH CIRCUIT OPINION UNDERMINES THE INTEGRITY OF A REGULATORY REGIME DESIGNED TO PROTECT THE HEALTH AND SAFETY OF AMERICANS.

The Eighth Circuit's decision in this case not only fails to pay appropriate deference to the FDA's interpretation of its own regulations (and to the views of a sister circuit), it affirmatively countenances deceit of government regulators and the gaming of a regulatory system primarily designed to ensure "the safety of those who use medical devices." *Medtronic*, 518 U.S. at 491. The need to promote honest and forthright behavior by regulated entities – particulary entities whose products directly affect the public health and safety – could hardly be greater. Yet, at a time of extraordinary public and congressional concern over corporate malfeasance, the Eighth Circuit has ruled that submission of a pretextual 510(k) does not violate the Medical Device Act. Because the decision severely frustrates the primary objective of that law, it deserves special scrutiny by this Court.

As the facts of *Buckman* demonstrate, the 510(k) process, which combines modest agency review with significant competitive advantages, creates incentives that can lead some manufacturers to game the system, with disastrous results for the public's health and safety. In *Buckman* itself, the manufacturer relied on the advice of a regulatory consultant, who hatched the strategy of limiting the labels for the bone screws to one form of surgery, even though the manufacturer intended and expected that the product would only be used for a different type of surgery. See *Orthopedic Bone Screws*, 159 F.3d at 820. Sophisticated consultants who help manufacturers navigate this complex regulatory regime will make use of the Eighth Circuit's decision to uphold a $75 million jury verdict that was based on the theory that it is permissible to file a pretextual 510(k) application. Coupled with this Court's preemption of common law fraud-on-the-agency claims, the Eighth Circuit's decision can only serve to induce

consultants and manufacturers to adopt Biomedical's "cover your flanks with labeling" approach to 510(k) submissions. This will increase the risk that new medical products that are unsafe for their actual intended uses will reach the public.

To be sure, the FDA has tools at is disposal to detect, deter and punish false statements made during the 510(k) process. The FDA is empowered to investigate fraud, 21 U.S.C. § 372; 21 C.F.R. § 5.35, and may respond by seeking injunctive relief or civil penalties, seizing the device, or even pursuing criminal prosecutions. See 21 U.S.C. §§ 333(a), (f)(1)(A), 334(a)(2)(D); see also, *e.g.*, *United States* v. *Barile*, 286 F.3d 749 (4th Cir. 2002) (involving prosecution for materially false statements made to the FDA on 510(k) submissions). But the agency cannot be expected to detect all misleading 510(k) submissions, and efforts to do so will divert agency resources from other important activities aimed at protecting and promoting the public health and safety.

Moreover, even if the agency succeeds in identifying all of the pretextual, "cover your flanks" 510(k) submissions that the Eighth Circuit's decision will yield, that decision will pose a significant barrier to successful punishment of such filings. A manufacturer charged with making a criminally false and misleading 510(k) submission will undoubtedly seek refuge in the Eighth Circuit's holding that it does "not . . . violate federal law" for a 510(k) applicant to omit the actual intended use of a new medical device. By casting doubt on the illegality of such conduct, the Eighth Circuit's decision will undermine the deterrence value of potential criminal sanctions.

In short, the decision below creates perverse incentives for manufacturers to circumvent FDA regulations, thereby undermining a regulatory regime designed to protect the public health and safety. As manufacturers take their cue from the Eighth Circuit, the FDA runs the risk of making equivalency determinations based upon incomplete, inaccurate, misleading and even fraudulent data. A holding

that so blatantly frustrates a regulatory scheme designed to protect the public health warrants this Court's careful review.

CONCLUSION

For the reasons stated above, the Court should grant the petition for writ of certiorari.

Respectfully submitted,

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October 17, 2002

APPENDICES

APPENDIX A

UNITED STATES COURT OF APPEALS
EIGHTH CIRCUIT

No. 01-3076

BIOMEDICAL SYSTEMS CORPORATION,
Appellee,

v.

GE MARQUETTE MEDICAL SYSTEMS, INC.,
Appellant.

Submitted: April 16, 2002.
Filed: April 23, 2002.

Before HANSEN, Chief Judge, McMILLIAN and FAGG, Circuit Judges.

PER CURIAM.

GE Marquette Medical Systems, Inc. (GE) appeals from an adverse jury verdict in this diversity action. Having carefully reviewed the briefs, record, and arguments of counsel, we are satisfied the district court * correctly applied state law, and the challenged rulings do not require reversal. Because the parties' submissions show they are thoroughly familiar with the issues before this court, we conclude that an extended opinion in this diversity case would serve no useful purpose.

Before GE acquired Corometrics, Inc. (Corometrics), Corometrics contracted to produce a new home uterine activity monitor (HUAM) based on technology developed by

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* The Honorable Charles A. Shaw, United States District Judge for the Eastern District of Missouri.

Biomedical Systems Corporation (Biomedical). (Because Corometrics is now part of GE, we refer to Corometrics as GE.) HUAMs are medical devices regulated by the Food and Drug Administration (FDA). The GE-Biomedical contract required GE to obtain "510(k)" premarket notification clearance from the FDA. *See* Food, Drug, and Cosmetic Act, ch. 675 § 510(k), 76 Stat. 794 (1962) (codified as amended at 21 U.S.C. § 360(k) (1994)). To receive 510(k) clearance, a manufacturer must give the FDA 90 days' notice that the manufacturer intends to market a medical device (1) which is substantially equivalent to a device already approved by the FDA, and (2) which has the same intended use as the approved device. *Id.* If the FDA agrees, it issues a clearance letter which authorizes the manufacturer to market the device as specified by the FDA.

Rather than seeking 510(k) approval, which would be granted or denied within 90 days, GE asked the FDA to reclassify GE's new HUAM from one class of regulated devices to another class of regulated devices. The reclassification process took three and a half years. Two and a half years after signing the contract, Biomedical sued GE in federal district court alleging fraudulent misrepresentation and breach of contract, and claiming $135 million in damages. The jury found for Biomedical on its breach of contract claim and awarded $75 million in damages. On appeal, GE challenges the district court's rulings barring its illegality and waiver defenses.

First, GE argues it was entitled to judgment as a matter of law because the contract, which GE drafted, required GE illegally to seek 510(k) approval for the new HUAM. Having reviewed this issue de novo, *Fogelbach v. Wal-Mart Stores, Inc.*, 270 F.3d 696, 700 (8th Cir.2001), we conclude the district court properly denied GE judgment as a matter of law on its illegality defense. In our view, the contract unambiguously required GE to apply for 510(k) clearance and did

not require GE to violate federal law. Indeed, after considering the contractual language in light of extrinsic evidence about the parties' intent when entering into the contract, the jury reached the same conclusion.

Second, GE contends the district court improperly excluded evidence that Biomedical waived GE's breach of the contract provisions requiring GE to seek 510(k) approval. The GE-authored contract, however, expressly forbids waiver of this sort. Because the contract is governed by Connecticut law under which the waiver provision is valid, *see Christensen v. Cutaia,* 211 Conn. 613, 560 A.2d 456, 459 (Conn.1989), we conclude the district court correctly barred GE's waiver defense.

Having satisfied ourselves that the district court correctly rejected GE's illegality and waiver defenses, we also reject GE's remaining arguments. Because the contract did not require illegal conduct on GE's part, we do not disturb the jury damage award. Further, the district court did not abuse its discretion when it excluded evidence that supported and refused to give requested instructions that explained the illegality and waiver defenses.

In sum, whether discussed or not, we have considered all of GE's arguments. Finding no error that would require reversal, we affirm the judgment of the district court.

APPENDIX B

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

[Filed Apr 10, 2001]

No. 4:99 CV-1590 CAS

BIOMEDICAL SYSTEMS CORPORATION,
Plaintiff,

v.

GE MARQUETTE MEDICAL SYSTEMS, INC.,
Defendant.

JUDGMENT

This matter came on for trial before a jury, the undersigned United States District Judge presiding. The issues were duly tried and the jury rendered its verdict on April 9, 2001, in favor of plaintiff Biomedical Systems Corporation and against defendant GE Marquette Medical Systems, Inc. on Count I, and in favor of defendant GE Marquette Medical Systems, Inc. on Count II.

Accordingly,

IT IS HEREBY ORDERED, ADJUDGED and DECREED that judgment is entered in favor of plaintiff Biomedical Systems Corporation and against defendant GE Marquette Medical Systems, Inc. on plaintiff's claims in Count I for breach of contract.

IT IS FURTHER ORDERED, ADJUDGED and DECREED that plaintiff Biomedical Systems Corporation is awarded actual damages on Count I in the amount of Seventy-Five Million Dollars ($75,000,000.00), together with post-judgment interest at the rate of 4.00 percent per annum, as provided by law.

IT IS FURTHER ORDERED ADJUDGED, and DECREED that judgment is entered against plaintiff and in favor of defendant GE Marquette Medical Systems, Inc. on Count II for fraudulent misrepresentation.

IT IS FURTHER ORDERED that costs are assessed against defendant GE Marquette Medical Systems, Inc.

/s/ Charles A. Shaw
CHARLES A. SHAW
UNITED STATES DISTRICT JUDGE

Dated this 10th day of April, 2001.

APPENDIX C

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

[Filed Jul 16, 2001]

No. 4:99-CV-1590 CAS

BIOMEDICAL SYSTEMS CORPORATION,
Plaintiff,

v.

GE MARQUETTE MEDICAL SYSTEMS, INC.,
Defendant.

ORDER

This matter is before the Court on the Motion of Defendant for Judgment in Accordance with Motion for Judgment as a Matter of Law, or in the Alternative, Motion for a New Trial, filed pursuant to Fed. R. Civ. P. 50(b) and 59.

The Court, after careful consideration, concludes that defendant's motion for judgment in accordance with its motion for judgment as a matter of law should be denied, and that defendant's alternative motion for new trial should be denied. Accordingly,

IT IS HEREBY ORDERED that defendant's motion for judgment in accordance with its motion for judgment as a matter of law is DENIED. [Doc. 203]

IT IS FURTHER ORDERED that defendant's alternative motion for new trial is DENIED. [Doc. 203]

/s/ Charles A. Shaw
CHARLES A. SHAW
UNITED STATES DISTRICT JUDGE

Dated this 16th day of July, 2001.

APPENDIX D

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No. 01-3076

BIOMEDICAL SYSTEMS CORPORATION,
Appellee,

vs.

GE MARQUETTE MEDICAL SYSTEMS, INC.,
Appellant.

Order Denying Petition for Rehearing and
for Rehearing En Banc

The appellant's motion to file a reply memorandum in support of its petition for rehearing en banc was granted, and the voting date on the petition was extended to permit all judges to consider the reply.

The petition for rehearing en banc is denied. The petition for rehearing by the panel is also denied.

Judge Morris S. Arnold and Judge Melloy took no part in the decision in this matter.

(5128-010199)

July 19, 2002

Order Entered at the Direction of the Court:

Clerk, U.S. Court of Appeals, Eight Circuit

APPENDIX E

21 U.S.C. § 360. Registration of producers of drugs or devices

* * * *

(k) Report preceding introduction of devices into interstate commerce

Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary or person who is accredited under section 360m(a) of this title (in such form and manner as the Secretary shall by regulation prescribe)—

(1) the class in which the device is classified under section 360c of this title or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

(2) action taken by such person to comply with requirements under section 360d or 360e of this title which are applicable to the device.

* * * *

(June 25, 1938, c. 675, § 510, as added Oct. 10, 1962, Pub.L. 87-781, Title III, §302, 76 Stat. 794, and amended July 15, 1965, Pub.L. 89-74, § 4, 79 Stat. 231; Oct. 27, 1970, Pub.L. 91-513, Title II, § 701(e), 84 Stat. 1282; Aug. 16, 1972, Pub. L. 92-387, §§ 3, 4(a) to (c), 86 Stat. 560 to 562; May 28, 1976, Pub.L. 94-295, § 4(a), 90 Stat. 579; Nov. 21, 1997, Pub.L. 105-115, Title I, § 125(a)(2)(C), Title II, §§ 206(a),

209(a), 213(b), Title IV, § 417, 111 Stat. 2325, 2338, 2341, 2347, 2379.)

21 U.S.C. § 360c. Classification of devices intended for human use

* * * *

(f) Initial classification and reclassification of certain devices

(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, is classified in class III unless—

(A) the device—

(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b) of this section, or (II) which was not so introduced or delivered before such date and has been classified in class I or II, and

(ii) is substantially equivalent to another device within such type, or

(B) the Secretary in response to a petition submitted under paragraph (3) has classified such device in class I or II.

A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) or (3) classifying the device in class I or II.

* * * *

(i) Substantial equivalence

(1)(A) For purposes of determinations of substantial equivalence under subsection (f) of this section and section 360j(*l*)

of this title, the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device—

(i) has the same technological characteristics as the predicate device, or

(ii) (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 360m of this title, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.

* * * *

(June 25, 1938, c. 675, § 513, as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 540, and amended Nov. 28, 1990, Pub.L. 101-629, §§ 4(a), 5(a), (b), (c)(1), (c)(3), 12(a), 18(a), 104 Stat. 4515, 4517, 4518, 4523, 4528; June 16, 1992, Pub.L. 102-300, § 6(e), 106 Stat. 240; Aug. 13, 1993, Pub.L. 103-80, § 3(s), 107 Stat. 778; Nov. 21, 1997, Pub.L. 105-115, Title II, §§ 205(a), (b), 206(b), (c), 207, 208, 217, 111 Stat. 2336, 2337, 2339, 2340, 2350.)

21 U.S.C. § 360e. Premarket approval

(a) General requirement

A class III device—

(1) which is subject to a regulation promulgated under subsection (b) of this section; or

(2) which is a class III device because of section 360c(f) of this title,

is required to have, unless exempt under section 360j(g) of this title, an approval under this section of an application for premarket approval.

(b) Regulation to require premarket approval

(1) In the case of a class III device which—

(A) was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976; or

(B) is (i) of a type so introduced or delivered, and (ii) is substantially equivalent to another device within that type,

the Secretary shall by regulation, promulgated in accordance with this subsection, require that such device have an approval under this section of an application for premarket approval.

* * * *

(June 25, 1938, c. 675, § 515, as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 552, and amended Nov. 28, 1990, Pub.L. 101-629, §§ 4(b)(1), 9(a), 18(c), 104 Stat. 4515, 4521, 4528; Aug. 13, 1993, Pub.L. 103-80, § 3(t), 107 Stat. 778; Nov. 21, 1997, Pub.L. 105-115, Title II, §§ 201(b), 202, 205(c), 209(b), 216(b), 111 Stat. 2334, 2338, 2341, 2349.)

APPENDIX F

21 C.F.R. § 801.4. Meaning of "intended uses."

The words "intended uses" or words of similar import in §§ 801.5, 801.119, and 801.122 refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the devices, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.

21 C.F.R. § 807.87. Information required in a premarket notification submission.

Each premarket notification submission shall contain the following information:

* * * *

(e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for

its use. Where applicable, photographs or engineering drawings should be supplied.

(f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

* * * *

[42 FR 42526, Aug. 23, 1977, as amended at 57 FR 18066, Apr. 28, 1992, 59 FR 64295, Dec. 14, 1994; 63 FR 5253, Feb. 2, 1998]

Supreme Court, U.S.
FILED
OCT 29 2002
CLERK

No. 02-606

IN THE

Supreme Court of the United States

GE MEDICAL SYSTEMS
INFORMATION TECHNOLOGIES, INC.,
Petitioner,

v.

BIOMEDICAL SYSTEMS CORPORATION,
Respondent.

On Petition for Writ of Certiorari
to the United States Court of Appeals
for the Eighth Circuit

RESPONDENT'S BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether this Court should grant certiorari to review the unanimous three-page per curiam affirmance of a jury verdict for breach of contract based on unique facts in a diversity case applying Connecticut law.

2. Whether under Connecticut law a party who drafted a contract can avoid the consequences of his breach by arguing that he would have chosen to perform the contract in an illegal manner.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, Respondent Biomedical Systems Corporation states that it is a privately-held corporation with no parent corporation and that no publicly-held company holds any portion of its stock.

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Beck & Azari, "FDA Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions," 53 FOOD & DRUG L.J., 71 (1998) 16

GAO Report to the Chairman, Committee on Labor and Human Resources, U.S. Senate, Off-Label Drugs at 11 (1991) 17

Hearing Before the Subcommittee on Human Resources and Intergovernmental Relations of the House Committee on Government Reform and Insight, 104th cong. 2d Sess. 61-62 (Sept. 12, 1996) 17

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STATEMENT OF THE CASE

The Question supposedly Presented by GE's petition is hypothetical, is not framed by the record in this case, and is predicated on "facts" that are contrary to the evidence. It asks the Court to decide what *would have happened* if GE had not breached its contract and in the course of performance had chosen allegedly to violate applicable laws and regulations. No manufacturer "sought" FDA action by submitting a "false application." Liability was imposed here by a Missouri jury for breach of contract under Connecticut law because GE unilaterally decided to disregard a provision in a written, integrated Agreement between the parties in favor of a regulatory process GE deemed more desirable — which ultimately took 3½ years.

The petition does not mention the constantly-changing excuses for its flagrant breach that GE offered during the course of this litigation, culminating with the implausible last-ditch assertion that the contract — which GE drafted — is "illegal." Both lower courts analyzed the contract under Connecticut law and quite reasonably held that it was enforceable because it did not have "a violation of law as its inherent purpose" and did not require acts which are prohibited by statute. *See Haynes Constr. Co. v. Cascella & Son Constr., Inc.*, 647 A.2d 1015, 1020-21 (Conn. App. 1994); *Burns v. Koellmer*, 527 A.2d 1210, 1213 (Conn. App. 1987). There was abundant evidence that GE could easily have honored its promise to Biomedical without violating any law or regulation.

Hence, petitioner's Question Presented is based on a hypothetical, non-existent scenario and is contradicted by abundant evidence accepted by the jury. Accordingly, we will review that evidence to place the petition in its proper context.

The Parties

Respondent Biomedical Systems Corporation is a family-owned Missouri corporation headquartered in St. Louis. It is engaged in the medical monitoring business, both cardiovascular and obstetrical.

Petitioner GE Medical Systems Information Technologies, Inc. is a wholly-owned subsidiary of General Electric Corporation. It is the successor to Marquette Medical Systems, Inc., which GE acquired in 1998, and to Corometrics Corporation, which Marquette acquired in 1997. Unless the context requires otherwise, we will refer to all of these entities as "GE" or "petitioner."

The HUAM Industry and 510(k) Clearance

This diversity case involves equipment used in the field of home uterine activity monitoring ("HUAM"). Hospitals and clinics have used uterine activity monitors since the 1960s to detect contractions either during labor or earlier if a pregnant patient is hospitalized with complications, such as pre-term labor. A HUAM is a portable version of the hospital-based monitor. The manufacturer simply adds a telephone modem to the device so that it can transmit data on contractions, fetal movement, and other uterine activity over telephone lines. This allows prescribing physicians to have access to critical information without admitting the patient to the hospital. The monitors, whether hospital-based or portable, cannot harm the patient and are used the same way whether a patient is pre-term or at term.

Since 1984, thirteen different HUAMs have been given clearance for marketing by FDA under its "510(k)" procedure. This 510(k) nomenclature is a shorthand reference to the speedy clearance process provided under §510(k) of the Federal Food, Drug & Cosmetic Act, 21 U.S.C. §360(k). FDA's formal name for the

510(k) process is "Premarket Notification." Section 510(k) allows a manufacturer to give FDA 90 days' advance notice that it intends to market a medical device that is substantially equivalent to another legally marketed device already cleared by FDA, including for the same use. If FDA agrees that the new device is substantially equivalent to the "predicate device," it then issues a 510(k) clearance letter to the manufacturer allowing it to market the device.

This Court noted in *Medtronics, Inc. v. Lohr*, 518 U.S. 470 (1996), that the 510(k) process is demonstrably faster than the more rigorous pre-market approval (PMA) procedure. A PMA review takes about 1200 hours, whereas a 510(k) review takes about 20 hours and is completed within 90 days. *Id.* at 478-79. Approximately 80% of new devices have been introduced into the market through the 510(k) process and without PMA review. *Id.* As the Court observed, "the 510(k) process is focused on equivalence, not safety." *Id.* at 493.

In 1990, GE's predecessor, Corometrics, decided to enter into the HUAM business. Corometrics obtained clearance to market its Model 600 through a 510(k) application it submitted to FDA. Even though Corometrics knew that its device would be used in connection with a pre-term birth prevention program, it filed an application with a "statement of intended use" that stated:

> "The Model 600 Uterine Activity Monitor is intended for home uterine activity monitoring of patients at term, *but is not intended for prediction of pre-term labor*. Both the device top panel and the Operations Manual are clearly labeled to this effect."

FDA cleared the Model 600 in 90 days but, as with other HUAMs, required Corometrics to affix a label stating:

> "Warning: Not to be used for prediction of pre-term labor as this use is considered investigational."

Off-Label Use

FDA began regulating medical devices in 1976. It does not regulate the practice of medicine, however, and cannot prevent physicians from using an approved medical device or drug for non-FDA-approved uses if the physician believes it will be helpful to the patient. Thus, even though uterine activity monitors were cleared by FDA for term use in hospitals and clinics, physicians could prescribe the monitors for pre-term use in the home setting. From a medical standpoint, the term and pre-term uses are really the same: they measure contractions.

A physician's prescription of equipment for uses not yet approved by FDA is called "off-label" use. Such off-label use is common throughout the practice of medicine. Most major insurance companies pay for HUAM monitoring for patients in high-risk pregnancies without regard to whether the physician has prescribed the monitor on- or off-label.

Biomedical developed its entire HUAM business using "AMS" monitors. AMS had obtained 510(k) clearance for its monitor by notifying FDA that its monitor was substantially equivalent to earlier monitors cleared for term use. The AMS monitors contained the same limiting label as Corometrics Model 600. The presence of the label did not inhibit physicians from prescribing the monitor to high-risk pregnant women for pre-term use. Still prescribed today for a variety of indications, the aging AMS monitor is 510(k) cleared only for term use.

In 1993, Biomedical sought to upgrade its monitoring equipment and decided to develop its own HUAM. Biomedical's new monitor was near completion by early 1996. The device was easier to use, transmitted data faster, and unlike the AMS, was Y2K compliant. In April 1996, Biomedical's chairman and his son met in Connecticut with representatives of petitioner to discuss a possible joint venture for the manufacture and marketing of the new monitor, christened the Model 770. Biomedical made it clear at that meeting that its participation was conditioned upon applying for and obtaining 510(k) clearance to take advantage of a "window of opportunity" in the marketplace. They were told by a top GE executive, "Don't worry, I'll take care of it."

The Technology Transfer Agreement

The contract in issue in this case, the Technology Transfer Agreement between Biomedical and GE dated January 28, 1997 ("Agreement"), was drafted by petitioner's lawyers. It required Biomedical to transfer its technology to petitioner, which in turn agreed to manufacture and sell the device to Biomedical at a discount. Petitioner also agreed to pay Biomedical a royalty on all other sales. Biomedical was precluded from selling the monitor.

Petitioner was charged with the contractual duty of obtaining regulatory approval. The Agreement in five different paragraphs used the term "510(k)" seven times; no other type of regulatory approval was mentioned. In paragraph 8, it provided that "Corometrics agrees that it will bear the full cost of the 510(k) submission. . . ." The Agreement also stipulated that it "shall be construed in accordance with the substantive laws of the State of Connecticut" (¶17).

The Breach

Despite the language of the Agreement, GE advised Biomedical in March 1997 that it had decided to pursue a different regulatory approval process called reclassification, rather than 510(k) clearance. As soon as he learned of the change in strategy, Biomedical's chairman called GE to protest. He was told that reclassification would take only a little longer than 510(k) clearance and that GE would provide sufficient monitors in the meantime to serve Biomedical's clientele. Neither promise was fulfilled.

In June 1997, petitioner submitted its reclassification petition pursuant to §513(f) asking FDA to reclassify HUAM monitors from Class III to Class II for preterm use only for a narrowly-defined patient population: women who had experienced prior pre-term deliveries. Petitioner never intended to limit the use of the device to women with a prior pre-term birth. Fewer than ten percent of the prescribed patients have had prior pre-term deliveries.

The reclassification petition was filed under §513(f), and no part of it purported to be filed under §510(k). When reclassification was ultimately granted in January 2001 — 3½ years later — FDA confirmed that no 510(k) application had been submitted and stated: "You do not need a 510(k) premarket notification."

GE gave varying reasons for seeking reclassification rather than 510(k) clearance. Until late in this lawsuit, however, it was never suggested to Biomedical that the reason for pursuing reclassification was that the pursuit of 510(k) clearance would be illegal. To the contrary, Maria Fouts, GE's regulatory guru, stated precisely the opposite in an internal memorandum:

> "As [I've told] you before, there is nothing barring us from submitting a 510(k) for term use. We are just limited to 'Term use' claims (e.g. in promotional brochures, literature, op manuals, etc.). . . .
>
> "I would presume that if we chose to file a 510(k) for the Model 770 the action that AMS took would be required of us. The benefit is that you have a product that you can legally market in the U.S. regardless of the petition, albeit with limited claims."

There was no evidence that anyone proposed to market the 770 monitor for pre-term use. Biomedical always understood that, after obtaining 510(k) clearance, the monitor would be labeled as cleared for term use only and that all of the promotional brochures, operational manuals, and other literature describing the monitor would avoid pre-term references. These limitations would be nothing new to Biomedical or GE, since the AMS monitor and the Model 600 that they had used, respectively, for years had the same labeling and limitations in their marketing materials.

Ultimately, rather than obtaining clearance to market the device by the summer of 1997, GE received reclassification for very limited pre-term use in January 2001. By the time the monitors became available, the entire marketing opportunity which provided the basis for the Agreement had evaporated.

Proceedings Below

Biomedical filed this action on October 8, 1999 in the United States District Court for the Eastern District of Missouri. Jurisdiction was based on diversity of citizenship under 28 U.S.C. §1332. GE filed an answer which included three affirmative defenses, none of which was illegality. GE's position from the outset of

the case was that the contract was ambiguous and that it contemplated a two-step process whereby it would first obtain a reclassification and later get 510(k) clearance. Its initial answer, which was on file for well over a year, simply suggested that Biomedical's interpretation of the supposedly "ambiguous" contract was "inconsistent" with the FDA regulations.

Nearly a year after the lawsuit was filed, GE moved to dismiss, alleging for the first time that the contract was illegal. The district court denied that motion in an unreported order. The trial began on March 19, 2001, and continued for 16 trial days. The district judge, having ruled the contract legal, rejected repeated efforts by GE to explain why it decided, after the Agreement was signed, that it was more appropriate, desirable, or "legal" to pursue reclassification rather than 510(k).

Biomedical presented expert testimony that it was damaged to the extent of $135,379,873 by reason of the 3½-year delay caused by GE's unilateral departure from the regulatory pathway specified in the contract.

The case was submitted to the jury on Biomedical's claims of breach of contract and fraud. On April 9, 2001, the jury returned a unanimous verdict against GE on the contract claim only and awarded Biomedical actual damages of $75,000,000. GE appealed to the Eighth Circuit, which heard oral argument on April 16, 2002. On April 23, 2002, a three-judge panel of the Court of Appeals with a combined 91 years of judicial experience unanimously affirmed the judgment in a three-page per curiam opinion that summarily rejected GE's "illegality" theory. The court concluded, based on the parties' familiarity with the record, "that an extended opinion in this diversity case would serve no useful purpose" (Pet. Apdx 1a). The entirety of its holding on

illegality comprises two sentences:

> "[W]e conclude the district court properly denied GE judgment as a matter of law on its illegality defense. In our view, the contract unambiguously required GE to apply for 510(k) clearance and did not require GE to violate federal law." *Id.* at 2a-3a.

GE's petition for rehearing and rehearing en banc was denied without a recorded dissent. *Id.* at 7a.

REASONS FOR DENYING THE PETITION

This is a garden-variety breach-of-contract case that found its way into federal court because the parties were of diverse citizenship. The ultimate state-law question framed by the distinctive facts in this litigation is whether the Agreement could be performed without the commission of an illegal act. The four federal judges who have examined this question had little trouble in concluding that GE's belated excuse for nonperformance — its "illegality" defense — was entirely bogus.

The decision below has none of the earmarks of certworthiness. It is so cryptic as to not permit of the ominous extrapolations predicted by the petition. In contrast to its characterization here, GE complained in its rehearing petition below about the "panel's failure to explain the basis for [its] decision. . . ." This case is uniquely dependent on its facts, which are not evident from the Court of Appeals opinion, and which not even GE pretends are commonplace or likely to recur. There is no conflict with any other judicial decision or with a proper reading of the governing statutes and regulations. Despite GE's overblown rhetoric, this case is not about safety. The 770 monitor poses no health risk whether it is used at 18 weeks, 28 weeks, or 38 weeks, and GE never uttered a word about safety at trial.

Finally, GE's extensive reliance on an FDA amicus brief filed several years ago in a different context bespeaks the dearth of meaningful authority supporting petitioner's position.

I. GE'S LATE-CONCEIVED "ILLEGALITY" DEFENSE IS BASELESS.

GE's original answer did not plead illegality; it merely stated that Biomedical's interpretation of the Agreement was "inconsistent" with the FDCA, regulations, and guidelines. Once GE's trial counsel realized the magnitude of the problem they were facing, the illegality theory was hatched and became the basis for defendant's motion to dismiss, which was filed almost a year after the lawsuit began.

Whether a contract is legal or illegal is obviously a question of law for the court. *Kaiser Steel Corp. v. Mullins*, 455 U.S. 72 (1982). Here, both lower courts quickly and astutely recognized that GE's illegality defense was specious. Every manufacturer in the HUAM industry — including GE itself — has a monitor that was cleared by FDA for term-use marketing pursuant to §510(k), despite common knowledge that HUAMs were often legally prescribed "off-label" for pre-term monitoring. The Agreement required GE to do nothing different from what it and other manufacturers had previously done to obtain 510(k) clearance for HUAMs.

A. This Case Is Not About Health or Safety.

GE's repeated references to health, safety, "extremely dangerous" medical devices, and potentially "disastrous results" are certified red herrings. There was no claim at trial — and no evidence — that a HUAM poses any health or safety threat to mother or fetus at *any* gestational age. Additionally, apart from the fact that

this case has never involved health or safety, both Congress and this Court have noted the limited role of §510(k) as a labeling provision and have required FDA to allow competition in the marketplace by giving quick-path marketing permission to follow-on manufacturers whose devices are substantially equivalent to already-cleared devices. FDA is more than able to root out health and safety problems, but where, as here, 13 other monitors have previously been cleared, the health and safety determination has already been made.

Furthermore, FDA has plenty of statutory ammunition to pursue manufacturers who promote products or devices for purposes for which they were not cleared. Such devices are deemed adulterated or misbranded under 21 U.S.C. §§ 331 or 351 and are subject to forfeiture and other sanctions.

Contrary to GE's florid embellishments, nothing in the Court of Appeals opinion serves as a road map for regulatory skullduggery. The opinion assumes familiarity with the underlying facts and is of no utility to a stranger to the record. The decision in this case does not purport to interpret any statutes or regulations and has no effect on FDA's ability to perform its Congressionally-mandated duties.

B. The Role of "Intended Use" in the 510(k) Process

GE's illegality argument boils down to the contention that an applicant for 510(k) clearance violates federal law if its "statement of intended use" does not include all potential uses of the device that it anticipates any person will engage in. GE's proferred excuse for breaching its contractual obligations thus embodies a badly distorted view of the regulatory process.

As GE acknowledges (Pet. 5), the manufacturer of the

device (here, GE) can establish that its device is "substantially equivalent" to an already-cleared predicate device if it has the same intended use as the predicate device. §360c(i)(1)(A). The intended use is the use for which the applicant is seeking clearance, and the only requirements are that the device is suitable for that use and that the applicant intends to limit its labeling and promotional efforts to that use.

Even if the manufacturer knows that the device will be prescribed by physicians for uses other than those labeled and promoted, it is not required to identify such uses as long as it does not plan to promote or market the device for those uses. As FDA told this Court in its amicus brief in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001):

> "Under the regulations, a manufacturer is not required to disclose every foreseeable use of a device that it secretly desires. Physicians often use medical devices for purposes that are not identified in the labeling, and manufacturers may seek Section 510(k) clearance for the use identified in the labeling without setting forth every possible off-label use to which the device might be put after it reaches the market." Brief of United States as Amicus Curiae, No. 98-1768, p. 15.

FDA further advised the Court that as long as the stated intended use is *bona fide*, the application would be false and misleading only if "at the time of the application a manufacturer plans to *promote and distribute* a device *exclusively*" for a use that is not disclosed. *Id.* (emphasis added). Hence the duty to reference an intended use in a 510(k) submission, by FDA's own declaration, is triggered by the manufacturer's planned *promotion*, not knowledge or anticipation, of an intended use. There is no evidence

in the record that either of the parties planned to promote the 770 monitor for pre-term use.[1]

According to §360c(i)(l)(E)(i), "any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 510(k)." Thus, Congress has mandated that at the application stage the intended use of a device is to be determined from the face of the request for 510(k) clearance, not from §801.4 of the regulations cited by GE (Pet. 6), or any other source. That is, for the purpose of 510(k) *clearance*, the intended use of a medical device simply is that specific proposed use for which the manufacturer claims substantial equivalence to a "predicate" device already in the marketplace.

GE argued below that §360c(i)(1)(E)(i) does not apply to this case because it was enacted in 1997 after the Agreement was signed. The legislative history reveals, however, that it reflects Congress's intent from the inception of the Medical Device Regulation Act ("MDA") in 1976. *See* S. Rep. No. 105-43, at 60 (1997). The Senate Report further explains that the section was meant to clarify Congress's long-standing intention that the FDA "not exceed its jurisdictional responsibilities by incorporating into the review process claims not before the agency for review consideration." *Id.*

In direct contrast to GE's argument based on the

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[1] GE's statement that "Biomedical promotes its monitoring services as appropriate for home use by pre-term women" (Pet. 11) is misleading. Biomedical's promotional materials introduced at trial describe a broad range of diagnostic and educational services it can provide in a pre-term birth prevention program. Such techniques may include self-palpation and nurse follow-up. Biomedical's materials most certainly made no pre-term claims or representations regarding the 770 monitor.

inapplicable §801.4, Congress pointed out that in the MDA:

> "Congress intended that device classification and approval decisions be made on the intended use of devices as described in labeling. Over the years, FDA has made pre-market regulatory decisions based on uses for devices that are unrelated to the intended uses set forth in labeling....
>
> "For pre-market notification submissions, the labeling proposed in the submission will be controlling of a device's intended use. If the intended use is the same or substantially similar to the intended use of a predicate device, then the device may be found sufficiently equivalent to the predicate. No considerations outside of the proposed labeling for the 510(k) device should bear on the question of whether or not the proposed labeling of the newer device is compatible with the labeling of the predicate device." *Id.* at 60-61.

GE is misusing §801.4. It is a *labeling* regulation unrelated to the 510(k) regulatory provisions. *See* 21 C.F.R. Part 801 (Labeling) as compared to 21 C.F.R. Part 807, Subpart E (Premarket Notification Procedures). By its own terms, §801.4 defines "intended use" only for purposes of "§§801.5, 801.119 and 801.122," none of which deal with premarket notification. To further dispel any doubt that §360c of the statute, and not §801.4, is the proper source for the meaning of "intended use" in this case, the Ninth Circuit has determined that "[t]he 'intended use' inquiry for determining 'substantial equivalency' focuses . . . on whether the intended use of the product is *similar* to that of a preexisting, legally marketed device." *United States v. Bowen*, 172 F.3d 682, 687 (9th Cir. 1999). The court concluded that §360c contains the definition of "in

tended use" for the purpose of 510(k) clearance, while citing regulation §801.4 as an example of a provision relevant only "*[i]n other circumstances*, [where] courts can continue to look beyond the product's label." *Id.* (emphasis added).

GE's suggested interpretation of "intended use" is misconceived for another reason. As its own reclassification petition reveals, the *only* intended use described by GE in that petition was the intent "to measure the duration, frequency, and relative pressure of uterine contractions in a home or outpatient environment." Precisely the same statement could be made regarding *any* HUAM, no matter what gestational age is involved, and there is no reason why the same statement by GE in a 510(k) submission would have been anything but completely accurate.

Using GE's own interpretation of "intended use," the "intended use" of an HUAM is always the same — it is only the patient population (or indications for use) that changes. The monitor is used always and only to measure contractions, whether the patient has completed 34, 36, or 38 weeks. Hence, even if the targeted patient group were misdescribed, that would not constitute a false statement of an "intended use" as defined by GE.

C. FDA Has No Authority to Deny 510(k) Clearance Based on Concerns About "Off-label" Use by Physicians.

Confining FDA's inquiry to "substantial equivalence" is consistent with the recognition that FDA has no jurisdiction to regulate the practice of medicine and that devices cleared for one use are often prescribed by physicians for different (or "off-label") uses. Congress has codified this limitation on FDA's jurisdiction in 21 U.S.C. §396: "Nothing in this Act shall be construed to

limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."

In *Buckman* this Court took note of the prevalence and acceptability of off-label use of devices cleared under 510(k). The Court again emphasized that the 510(k) process "requires only a showing of substantial equivalence to a predicate device" and observed that "... 'off-label' usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." 531 U.S. at 348, 350.

The Court explicitly recognized the desirability of allowing manufacturers to apply for 510(k) clearance of medical devices for one use, while knowing that they would be prescribed for other uses by doctors, as one reason for prohibiting private fraud-on-the-FDA claims:

> "Would-be applicants may be discouraged from seeking 510(k) approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates... to unpredictable civil liability." *Id.* at 350.

The *Buckman* opinion twice cites an article by Beck & Azari, "FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions," 53 FOOD & DRUG L.J. 71 (1998), in which the authors point out that courts, several states, and "FDA itself recogniz[e] the value and propriety of off-label use" and that "[o]ff-label use is widespread in the medical community and often is essential to giving patients optimal medical care,

both of which medical ethics, FDA, and most courts recognize." *Id.* at 72, 76-77.

FDA itself has testified before Congress that "FDA recognizes that, in certain circumstances, off label uses ...can be of great value. Some off-label uses have been of great historical importance." *Hearing Before the Subcommittee on Human Resources and Intergovernmental Relations of the House Committee on Government Reform and Oversight*, 104th Cong., 2d Sess. 61-62 (Sept. 12, 1996) (statement of Michael Friedman, Deputy FDA Commissioner). And the agency has repeatedly and consistently reaffirmed the value, propriety, and legality of off-label use. *See* 59 Fed.Reg. 59,820 (Nov. 18, 1994); 52 Fed.Reg. 8798 (Mar. 19, 1987); 48 Fed.Reg. 26,720 (June 9, 1983); 40 Fed.Reg. 15,392, (Apr. 7, 1975); 37 Fed.Reg. 16,503 (Aug. 15, 1972). "It is not the [FDA's] policy, intent, or bias to indicate that off-label uses are wrong, improper, or even investigational." *GAO Report to the Chairman, Committee on Labor and Human Resources, U.S. Senate, Off-Label Drugs* at 11 (1991).

At trial, Dr. John P. Elliott, perhaps the foremost obstetrician in the country dealing with high-risk multiple pregnancies, told the jury that he regularly uses HUAMs for detection and treatment of pre-term contractions and that *all* the drugs he uses to discourage premature labor are off-label. He said that "the FDA actually totally supports this use of off-label indications for an approved drug" and that off-label use "is what I do for a living. So it's absolutely what is done in this country today." Dr. Elliott has used HUAMs on more than 1500 patients as a "useful tool" to help prevent prematurity and has never had an issue arise over such usage.

Thus, the role of FDA in reviewing 510(k) submis

sions, apart from the technology evaluation, is simply to determine whether the proposed marketing and promotional uses are substantially equivalent to those of another device already in the marketplace. FDA may not deny 510(k) clearance based on a concern that the device may be used off-label by the medical community, but it may deal with that concern by requiring the manufacturer to specify the limitations on use of the device. The line of demarcation under the statute is clear: FDA dictates label requirements; doctors practice medicine.

D. FDA's Treatment of Previous 510(k) Applications for HUAMs

Before GE and Biomedical signed the Agreement in January 1997, the market was being served almost exclusively by some of the 13 HUAMs previously cleared for term use under 510(k). Of special significance is the fact that GE's predecessor Corometrics (the signatory to the contract with Biomedical) had applied for and received 510(k) clearance for its Model 600 in 90 days in 1990.

Despite repeated denials by GE that the Model 600 was ever sold commercially, the evidence unmistakably established that at least $100,000 worth of those monitors were sold for use in pre-term evaluation. GE has never turned itself in to the U. S. Attorney as a result of these facts, nor has it offered to refund any of its would-be "ill-gotten" gains. For its part, Biomedical was using the AMS monitor in servicing patients for whom it was prescribed, and that device was regularly prescribed for pre-term ("off-label") use by obstetricians around the country. All its competitors also had monitors in the marketplace that had received quick-path clearance under 510(k). There was nothing "pretextual" about any of those 510(k) applications, and

FDA has never asserted that any HUAM was adulterated or misbranded.

It was against this backdrop that the parties agreed to do what GE had done before in order to get the improved 770 monitor to market while the window of opportunity was open. Biomedical simply wanted the same treatment for the 770 monitor that all competing products had received; and an internal memo from GE's senior regulatory affairs specialist acknowledged "there is nothing barring us from submitting a 510(k) for term use."

Confronted with a marketplace rife with 510(k)-cleared HUAMs being used by physicians for pre-term diagnosis, and relegated to a trumped-up "illegality" defense because of its obvious failure to perform a contractual undertaking, GE struggled at trial to suggest that the "regulatory climate" had changed at FDA after 1992. GE's statement that no HUAMs were 510(k)-cleared after 1992 (Pet. 9) ignores the fact that no 510(k) applications were *filed* during that period. And the 1999 panel report, upon which GE relies so heavily (and which was never sent to Biomedical), does not reflect a change of official policy but merely confirms that the 510(k) process is not available for pre-term *promotion*. Even if, as GE argues, FDA "invited" HUAM manufacturers to apply for reclassification, FDA had no discretion to reject a proper 510(k) application limited to term-use marketing. GE was bound by its contractual promise and was not free to follow a different route merely because its regulatory people wanted to curry more favor with the regulators. There was no change in the applicable statutes or regulations under which 13 other HUAMs had been 510(k) cleared. On the contrary, the enactment of §396 and the passage of §360c(i)(1)(E) in 1997 confirmed that Congress wanted

FDA to stick to its knitting and not become a policeman against off-label use.

E. GE Could Have Applied For — and Undoubtedly Would Have Received — 510(k) Clearance for Term Use Without Committing any Illegal Act.

All GE had to do to obtain 510(k) clearance for the 770 monitor was to show FDA that the 770 was substantially equivalent to other devices already legally marketed for term use. *That fundamental fact is undeniably true.* Such a statement of intended use — coupled with appropriate labeling disclaiming approval for preterm use — was precisely the approach followed by FDA in clearing at least 13 previous HUAMs pursuant to 510(k). The agency's action in those cases confirms the vacuity of GE's attempt to avoid the consequences of its breach by a *post-hoc* plea of illegality. Could FDA sponsor prosecution in 1997 for the same acts by the same party (and 12 others) it had blessed previously? *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43, 57 (1983) (agency changing its course must supply reasoned analysis, and agency action is arbitrary and capricious if agency has relied on factors which Congress has not intended it to consider).

If GE, as the manufacturer, had been truly concerned about the accuracy or "legality" of a statement of intended use identifying term patients only, then GE's proper course of action would *not* have been to break its promise to Biomedical but simply to limit its own marketing, labeling, and promotion to term use, as it had previously done with its Model 600. Moreover, under ¶ 12 of the Agreement, GE had a veto over any proposed "product labeling, literature and advertising" of the monitor and thus could have controlled Biomedical's promotional activities. But GE had no

cause for concern because Biomedical was willing to comply with any restrictions attached to 510(k) clearance, as it was already doing with regard to the AMS monitor. As stated previously, there was no evidence that anyone intended to promote or market the 770 for pre-term use.

GE could have fulfilled its contractual undertaking without saying anything even arguably false. It is no answer for GE to say that it did not intend to market the 770 for term use. It had agreed with Biomedical to apply for 510(k) clearance, and if that required GE to limit its promotion to term use, it had a contractual obligation to do so. A party cannot avoid its contractual obligations by arguing that it would have chosen to perform them in an illegal manner.

Finally, GE's illegality argument backfires because its own reclassification petition sought Class II treatment for pre-term patients *only if they had previously experienced a pre-term delivery*. The FDA Reclassification Order finally received in January 2001 therefore was limited to use for "Women with a clinical history of previous pre-term birth . . . . [Y]ou may not label or promote this monitor for any other indication for use." This category of permitted use encompasses fewer than 10% of all applications for which monitoring might be appropriate. The most common risk factors, such as multiple gestation, are still off-label. So, according to GE's logic, since it anticipated that physicians would prescribe the 770 for multiple gestation — by far the most pervasive use — its FDA filing was just as "false" as if it had been limited to term use. GE is thus ensnared by its own disingenuous advocacy.

F. A Claim of Illegality by the Party Who Drafted the Agreement Should Be Viewed Skeptically.

The irony and distastefulness of a party to a contract seeking to avoid its obligations by claiming it had agreed to break the law have not escaped judicial attention. In *Kelly v. Kosuga*, 358 U.S. 516, 519 (1959), the Court noted the observation in *McMullen v. Hoffman*, 174 U.S. 639, 669 (1899): "It has been often stated in similar cases that the defense [of illegality] is a very dishonest one, and it lies ill in the mouth of the defendant to allege it . . . ." The Court cautioned that "the federal courts should not be quick to create a policy of nonenforcement of contracts beyond that which is clearly the requirement of [a particular federal statute]." 358 U.S. at 519.

The remark from *McMullen* is especially apropos here. GE drafted the Agreement in which it promised Biomedical to do something that GE itself and many others had done before with agency approval. GE's own regulatory specialist admitted that "there is nothing barring us from submitting a 510(k) for term use." GE never took the position that its promise was illegal until it was faced with irrefutable evidence of a breach and had no other hole to crawl into. But neither the subject matter of the contract nor the consideration given required the commission of an act that could be deemed unlawful.

In sum, GE's promise to seek 510(k) clearance for the 770 monitor for term use was not illegal under Connecticut law. A statement that the monitor was substantially equivalent to other devices already on the market for term use would have been completely true, and at least 10% of the anticipated use was at term. The purpose of the 510(k) submission was to enable FDA to

determine only whether GE's stated intended use was substantially equivalent to the intended use of another device already in the market.

Furthermore, a statement that a HUAM was intended for term use would not be false unless the applicant had no intent whatsoever that monitors would ever be used by expectant mothers past their 36th week or, conversely, as phrased by FDA, unless they were marketed and promoted "exclusively" for pre-term use. And since FDA's role in processing 510(k) submissions is confined to determining "substantial equivalence" to existing devices, a failure to list legitimate off-label intentions of physicians would not be "material" to the agency's function, as required for a criminal offense.

GE has pointed to no case — and we have found none — where a 510(k) applicant has ever been charged with a criminal offense based on a statement of intended use.[2] In light of the prevalence and legality of off-label use, which is well known to and actually anticipated by FDA, any such prosecution would be ill-founded and in bad faith. And the medical, pharmaceutical, and medical device communities would surely be shocked and outraged by such action, especially considering the literally millions of off-label prescriptions written daily.

II. THE DECISION BELOW DOES NOT CONFLICT WITH ANY OTHER DECISION.

GE tries to conjure up a circuit conflict by invoking the decision in *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817 (3d Cir. 1998), *rev'd sub nom. Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341

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[2] The unsuccessful prosecution in *United States v. Barile*, 286 F.3d 749 (4th Cir. 2002), was not based on an intended use statement but on an allegedly false statement that the proposed device had been properly tested.

(2000). That was a class action by thousands of individuals claiming that the defendant had committed fraud on the FDA in connection with 510(k) clearance for orthopedic bone screws. After the district court had sustained a Rule 12 motion to dismiss, the Third Circuit, in a 2-1 "narrow" decision, reversed, holding that fraud-on-the-FDA claims should not be dismissed at the pleading stage and were not pre-empted by the MDA. 159 F.3d at 829.

GE's reliance on *Orthopedic Bone Screw* for a conflict is misplaced for a number of reasons: (1) that case arose in a completely different setting — thousands of multidistrict tort cases before the court on the pleadings in a pre-emption context, rather than, as here, a solitary private contract case after a three-week jury trial; (2) the statements by the Third Circuit relied on by GE were dicta not encompassed within the court's "narrow" holding; [3] and (3) the Third Circuit's judgment was reversed outright by this Court in *Buckman*, not "on other grounds," as GE suggests. The statements relied on by GE from the Third Circuit opinion were central to that court's view of the law, which was completely overturned by this Court. The Court of Appeals' premises fell with its conclusion, and the Third Circuit opinion is a nullity that affords no basis for asserting an inter-circuit conflict.[4]

Moreover, as pointed out earlier, this Court expressly endorsed off-label use and refused to permit fraud-on-the-FDA claims based on off-label use because:

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[3] Indeed, the alleged "holding" quoted on page 15 of the petition is actually nothing but a recitation of the plaintiffs' allegations. *See* 159 F.3d at 828.

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[4] Apparently for these reasons, *Orthopedic Bone Screw* was not even cited in GE's opening brief in the Eighth Circuit.

"Would-be applicants may be discouraged from seeking 510(k) approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates... to unpredictable civil liability." *Buckman*, 531 U.S. at 350.

III. GE'S RELIANCE ON FDA'S AMICUS BRIEF IN *BUCKMAN* IS INAPPROPRIATE AND, IN ANY EVENT, PRESENTS NO ISSUE WORTHY OF THIS COURT'S REVIEW.

Devoid of any case law supporting its position, GE adopts a decidedly unorthodox approach by relying extensively on an amicus curiae brief filed by an administrative agency in another case where its processes were directly involved and where the Court expressly requested its participation. GE's reliance on the FDA amicus brief in *Buckman* is unavailing and at most asks the Court to apply its prior decision in *Auer v. Robbins*, 519 U.S. 452 (1992), to the esoteric facts of this case and in the absence of any split in the circuits on the applicability of *Auer* in these circumstances.

In the first place, FDA has specifically disclaimed any interest in commenting on the issues in this lawsuit or influencing its outcome. GE requested testimony from FDA in this case but was flatly rejected in writing. FDA told GE that there were no "compelling circumstances" justifying agency participation in this case; that such participation would not be in the public interest; that it wants "to avoid the impression that FDA, or one of its employees, is taking a partisan position in litigation where, as here, the agency is not a party"; and that "the proposed testimony would not promote the objectives of the FFDCA." The agency's position not only suggests the inappropriateness of GE's reliance on the *Buckman* amicus brief but also

belies GE's hyperbolic invocations of health and safety concerns.

Second, GE's citation of *Auer* is off-target. In *Auer*, the agency whose regulations were squarely before the Court for interpretation in a concrete dispute was, again, specifically requested by the Court to give its views as amicus on the merits of the pending case. That is a far cry from GE's attempted utilization of an amicus brief from a different case raising completely different issues. *Buckman* involved a wholesale attempt to subject FDA's procedures to second-guessing by civil juries and threatened the primacy of the statutes under which FDA operates. In contrast, none of the agency's 510(k) machinery was even invoked in this business dispute between two private corporations. None of the agency's regulations have been interpreted in the present case, and petitioner is asking for a ruling on a hypothetical set of facts, *i.e.*, what would have happened if GE hadn't breached the Agreement? In any event, it is inappropriate to ascribe a viewpoint to FDA on completely different facts from those in *Buckman*, especially in light of its unequivocal refusal to participate in this case. The Eighth Circuit did not mention *Auer* or the FDA amicus brief in its opinion and did not err in refusing to apply *Auer*. But even assuming otherwise, no split in the circuits exists regarding how *Auer* should be applied to such a fact-intensive private dispute as is presented here.

Finally, even discounting the self-serving interest of a federal agency in expanding its jurisdiction, the *Buckman* amicus brief does not help GE. The FDA *Buckman* brief suggests that when a device is to be promoted *exclusively* for one use, that use must be disclosed by the manufacturer to FDA. Here, the only promotion of the 770 monitor referred to in the evidence

was for term use. FDA's analysis of "intended use" in the *Buckman* brief is mistaken because it is predicated on §801.4, which, as noted above, is a labeling regulation that does not apply to the 510(k) application process. *Bowen*, 172 F.3d at 687. And to the extent FDA claims the province of looking behind the statement of intended use to police off-label use, it runs afoul of § 360c(i)(1)(E)(i).

But even postulating the contrary for the sake of argument, (a) the Model 770 was not to be used exclusively for pre-term patients; (b) the amicus brief expressly disclaims "knowledge" as defining the need for identifying uses; (c) §801.4 permits the manufacturer to protect itself against the consequences of subsequent off-label use by "provid[ing] adequate labeling for such a device which accords with such other uses to which the article is to be put"; and (d) in any event, GE could have avoided breaching the Agreement by filing a 510(k) for term use of the 770 monitor while pursuing a PMA application or a reclassification petition for pre-term use on a separate track.

GE never contended at trial that the 770 monitor was to be used "exclusively" for pre-term patients but instead characterized pre-term as the "vastly predominant" use. The evidence showed that Biomedical monitors term as well as pre-term patients. Many of the patients Biomedical now serves with the AMS 510(k)-cleared monitor do indeed use them through term. It therefore would have been perfectly proper for GE to label and promote the intended use for the 770 as being for term patients as it contracted to do; indeed, such a statement could only be false if the device *could not* be used at all for term patients.

In sum, the FDA amicus brief in a different case raising completely different issues is too thin a reed

upon which to hang a request for review by this Court. Moreover, the FDA position, properly construed, does not undermine the conclusion reached by the two lower courts and the jury.

CONCLUSION

For the reasons stated, the petition for writ of certiorari should be denied.

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IN THE

Supreme Court of the United States

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC.,
Petitioner,

v.

BIOMEDICAL SYSTEMS CORPORATION,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit

REPLY BRIEF OF PETITIONER

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REPLY BRIEF OF PETITIONER

As respondent's opposition unwittingly confirms, this case squarely poses the question whether a manufacturer can submit a 510(k) notification that claims an intended use for a medical device that the manufacturer has no intention of promoting, and for which no physician will ever prescribe the device. Indeed, respondent spends most of its brief arguing that federal law permits the filing of such a pretextual 510(k) notification, that the contrary views of the Third Circuit and the Food and Drug Administration ("FDA") are "dicta" or "mistaken," and that such a deceptive notification poses no health or safety concerns. As GE demonstrates below, respondent's arguments serve only to underscore that the petition raises an important question of federal law that warrants plenary consideration by this Court. The "cryptic" nature of the Eighth Circuit's opinion provides no justification for declining to review a deeply flawed *holding* that conflicts with the ruling of a sister circuit, and with the views of an agency, on a question of federal law crucial to the public health and safety.

1. Although respondent suggests that this case involves questions of state law, its entire argument is that GE would not have violated *federal law* by filing a 510(k) notification for term use as long as GE limited its labeling and promotional efforts to use of the monitor by women whose pregnancies have already reached full term. In making this claim, moreover, respondent expressly concedes or fails to contest these essential facts: (1) Its prior HUAM "was *regularly prescribed for pre-term* . . . use by obstetricians around the country." Br. at 18 (emphasis added). (2) The marketplace is "rife with . . . HUAMs being used by physicians for pre-term" use. *Id.* at 19. (3) The *only* use for its new HUAM identified in the complaint was pre-term monitoring. (4) Every penny in damages that respondent sought – and that the jury awarded – was for pre-term use. (5) Respondent's own medical expert testified that he had

never used a HUAM for term use, and instead "*regularly uses* HUAMs for detection and treatment of *pre-term* contractions." *Id.* at 17 (emphases added). (6) GE's expert testified that he could not imagine why anyone would ever prescribe a HUAM for term use. (7) Respondent offered no evidence that any physician ever prescribes HUAMs for term use.[1]

These uncontested facts thus give rise to a fundamentally important question of federal law that directly affects the ability of the FDA to protect the public health and safety: can a manufacturer lawfully file a 510(k) notification for a particular intended use, with "labeling disclaiming approval for" another use, Br. at 20, even though it knows that the *only* market for the device is for the *unlabeled* use, and that no physician would ever prescribe it for its labeled use. There is nothing "hypothetical" about this legal question, *id.* at 1, which is why respondent devotes so much of its opposition to defending the lower court's resolution of the question. That effort is not only unavailing, it illustrates the conflict the decision below creates with the holding of a sister circuit and with the FDA's authoritative construction of its own regulations and the laws it enforces.

2. In an attempt to show that a 510(k) can lawfully claim an "intended use" for which no physician will ever prescribe the device, respondent argues here, as it did below, that the "intended use" is only "the use for which the applicant is *seeking clearance*," and thus must be determined only "*from the face of the request for 510(k) clearance*, not from [the FDA] regulations cited by GE (Pet. 6) or any other source." Br. at 12-13 (emphases added). This legal contention – which

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[1] The fact that 10% of the *pre-term* patients for whom HUAMs are prescribed continue to wear them after they reach term, Br. at 22, 27, is not evidence that the device is *intended* for term use, anymore than casts, which are not removed until after broken bones heal, are prescribed or "intended" for use on unbroken bones.

is the basis of the Eighth Circuit's holding below – has been rejected by both the Third Circuit and the FDA.

a. In *In re Orthopedic Bone Screw Products Liability Litigation*, 159 F.3d 817 (3d Cir. 1998), *rev'd on other grounds*, *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the manufacturer argued, like respondent here, that "a statement of intended use is not a representation of fact or intent but, rather, a request for authority" – *i.e.*, a request for "clearance" – that enables the FDA "to limit the authority granted to that which is sought and considered by the agency." *Id.* at 827. In other words, the manufacturer argued that "intended use" is simply the use for which the applicant *seeks clearance*. The Third Circuit flatly rejected this claim, stating that, "[t]o the extent [the manufacturer's] argument is an assertion of law, we find no basis for it in the statute, in the regulations, or in any of the authorities cited." *Id.* at 828.

Confronted with a square circuit conflict, respondent argues that the Third Circuit's disposition of the manufacturer's "intended use" claim was simultaneously "dicta" and a "central" aspect of the decision that this Court overruled. Br. at 24. Both assertions are incorrect. The Third Circuit's resolution of the "intended use" argument was indisputably an essential holding of the case. The manufacturer argued that, because a statement of "intended use" is merely a request for clearance authority (and not an expression of marketing intentions), such a statement cannot mislead the FDA, and thus cannot give rise to any state law fraud claims, even if the manufacturer knows the device will only be used for a different purpose. See 159 F.3d at 826. Resolution of this issue was thus a necessary predicate to the court's preemption holding. Unless the intended use statement could have served as a basis for a state law claim of fraud, there would have been no state law claims to preempt.

It is likewise clear that this Court did not overturn the Third Circuit's predicate holding concerning "intended use." Had

this Court done so, it, too, would have had no reason to reach the preemption question. In fact, the central premise of the Court's preemption analysis was that fraud had occurred, but that it was the FDA's job "to police" it. *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). Thus, the Third Circuit's holding that a statement of intended use is not merely a representation of the clearance authority a manufacturer seeks, but also a statement that must truthfully reflect the manufacturer's actual intent, remains good law, and the decision below plainly conflicts with that holding.

b. The FDA has also squarely rejected the argument that "intended use" is merely the use for which the applicant is seeking clearance, and must therefore be determined from the face of the request for 510(k) clearance alone. Indeed, the FDA told this Court precisely the opposite in *Buckman*.

Citing the very regulation respondent deems irrelevant to the 510(k) process, the FDA explained that "the 'intended use' of a medical device is defined by the 'objective intent of the persons legally responsible for the labeling.'" Brief of *Amicus* Food and Drug Administration at 14, *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (No. 98-1768) ("FDA *Amicus* Br.") (quoting 21 C.F.R. § 801.4). The agency identified a number of factors extrinsic to the label that are relevant to determining the manufacturer's "objective intent," including "'the circumstances surrounding the distribution of the article'" and "'knowledge' that a product is 'offered and used for a purpose for which it is neither labeled nor advertised.'" *Id.* Thus, the FDA stated that, when it "seeks from [a 510(k)] applicant a statement of a device's intended use, it is *not* simply asking for the use that will appear on the labeling," and that the contrary contention advanced by Buckman (and now respondent) "misreads . . .

the applicable federal standards." *Id.* at 14-15 (emphasis added).[2]

Importantly, the FDA also explained, contrary to respondent's claim here, that § 360c(i)(1)(E)(i) "does not relieve manufacturers of their obligation . . . to truthfully inform FDA of a device's 'intended use' as that term is defined in FDA's 'intended use' regulation." *Id.* at 15 n.2. The agency noted that, in order to protect against "potentially harmful intended uses," the FDA is authorized to require statements regarding "'a use of the device not identified in the labeling.'" *Id.* at 16 n.2 (quoting § 360c(i)(1)(E)(i)(I)). This authority, the FDA explained, makes no sense unless the FDA can determine intended use from evidence outside the label itself.

It is thus clear that, in the expert judgment of the FDA, GE would have violated federal law by filing a 501(k) notification for term use. GE plainly had "'knowledge'" that the HUAM would be exclusively "'offered and used for a purpose for which it is neither labeled nor advertised.'" *Id.* at 14. Indeed, as respondent itself states, it was "common knowledge" that HUAMs are "regularly prescribed for pre-term ('off-label') use," Br. at 10, 18, and that they are *never* prescribed for term use. Given these facts, it is simply indisputable that a 510(k) notification for term use would not have been "bona fide," and instead would have been "a

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[2] The FDA's brief thus completely refutes respondent's claim, Br. at 14, that the "intended use" regulation, § 801.4, is unrelated to the 510(k) process. In fact, respondent's contention that § 804.1 "defines 'intended use' only for purposes of '§§ 801.5, 801.119 and 801.122,'" *id.*, is absurd. Section 804.1 states that it defines the phrase "intended uses *or words of similar import in §§ 801.5, 801.119, and 801.122.*" 21 C.F.R. § 801.4 (emphases added). These three identified regulations do not actually use the phrase "intended use." Thus, under respondent's reading, § 801.4 does not define the phrase "intended use" in any of the provisions that actually use that phrase.

pretext calculated to clear the device for distribution for other uses." FDA *Amicus* Br. at 15.

Respondent's facile observation that the facts of this case are different from those in *Buckman*, Br. at 26, in no way alters this conclusion. The *legal* issue that the FDA addressed in *Buckman* – the obligation to disclose the actual, bona fide intended use for a device in a 510(k) notification – is identical to the *legal* issue in this case. There is nothing "hypothetical," *id.*, about the Eighth Circuit's ruling that GE would not have "violate[d] federal law" by filing a 510(k) notification that disclosed an intended use for which no doctor would prescribe the device. App. 2a-3a. And in rendering this judgment, the lower court necessarily did interpret the FDA's regulations, cf. Br. at 26: it rejected GE's arguments, based on the FDA *Amicus* Brief, that a 510(k) notification for term use would have been an unlawful pretext under the agency's regulations.

Finally, it is fanciful to suggest that the FDA's routine refusal to permit one of its employees to testify as a witness in the proceedings below demonstrates that the legal issue raised by this case is of no concern to the agency. See Br. at 25-26. The FDA denied such permission "[b]ecause of FDA's limited resources and the vast number of requests the agency receives." See Reply App. 2a; see also 21 C.F.R. § 20.1. Nowhere did it state that the proper interpretation of its "intended use" regulation and the statutes governing the 510(k) process were unimportant. Should the Court harbor any doubts concerning the importance of these matters to the agency's fulfillment of its mission, the proper course would be to solicit the government's views on the subject.

In short, the Eighth Circuit's interpretation of the 510(k) regulations and statutes is fundamentally inconsistent with the interpretation rendered by the agency charged with administering them, and with the judgment of the Third

Circuit.[3] This Court should grant the petition in order to resolve this conflict over the obligations of a manufacturer seeking 510(k) clearance.[4]

3. Alternatively, respondent attempts to brush aside the FDA's expert views as an impermissible effort by the agency to "expand[] its jurisdiction," Br. at 26, and "become a policeman against off-label use" *Id.* at 20. These arguments confirm that, contrary to respondent's claims, the decision below involves very significant health and safety issues that underscore the necessity of this Court's review.

Throughout its opposition, respondent repeatedly asserts that, "[f]rom a medical standpoint," a HUAM is "use[d]" in precisely the same manner for pre-term and term patients, *id.* at 4; see also *id.* at 2, 15; that the device poses no safety threat to a pre-term woman, *id.* at 2, 10; and that pre-term monitoring is a common form of off-label use for the many monitors that were cleared for term use only. *Id.* at 17-19. These assertions fly in the teeth of the contrary views of the FDA itself. As GE has explained, between 1980 and 1992, the FDA cleared a number of HUAMs for term use. See at Pet. 8-9. Although the FDA lacks authority to regulate off-label prescriptions of medical devices once the devices are cleared, 21 U.S.C. § 396, it can and does keep abreast of the

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[3] Contrary to respondent's claim, Br. at 21, GE's bundled reclassification petition and 510(k) notification were not "illegal" under the view of the law adopted by the FDA and Third Circuit. GE sought reclassification for a HUAM intended for use on pre-term patients who had previously experienced a pre-term delivery. This is indisputably a bona fide use for which physicians will actually prescribe the device, not a pretext. GE's filing, moreover, confirms that, properly construed, the contract did not require anyone to "break the law," *id.* at 22-23, and instead required the entirely legal act of filing a bona fide 510(k) notification together with a petition for reclassification.

[4] As the petition itself makes clear, the issue presented concerns the obligations of manufacturers seeking 510(k) clearance, not the applicability of *Auer*, as respondent asserts. Br. at 25-26.

manner in which cleared devices are used. The FDA did precisely this with respect to HUAMs, and found that use of these devices to monitor pre-term patients raised new and unexpected health and safety risks.

While the devices themselves did not directly harm pre-term patients, Br. at 2, 10, the FDA found that they increased the risks of false positives, which in turn often resulted in unnecessary hospitalizations, risky drug treatments, and harmful patient stress. Obstetrics and Gynecology Devices; Reclassification of Home Uterine Activity Monitor, 64 Fed. Reg. 41,435, 41,437 (July 30, 1999). Accordingly, the FDA determined that use of HUAMs for the detection of pre-term labor was a new intended use, and that, for this new use, "the HUAM was not substantially equivalent" to any previously cleared device. *Id.* at 41,436. On the basis of these health and safety findings, the FDA classified HUAMs as Class III devices, and advised manufacturers that it would no longer clear the device for pre-term use unless the device "was reclassified . . . or subject to an approved PMA." *Id.*[5]

This decade-long evolution in the way in which HUAMs were used and in the FDA's clearance policy demonstrates that respondent was not entitled to "the same treatment for [its new] monitor that all competing products had received," Br. at 19, and that the FDA had not already determined that respondent's monitor was safe. Br. at 11. These changes in use and regulatory policy also completely refute respondent's claim that, because other HUAMs had been cleared for term use prior to 1992, the filing of a 510(k) for term use in 1997 would not have violated federal law. Prior to 1992, a statement of intended use for term monitoring would not have

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[5] Respondent disingenously claims that GE "never uttered a word about safety at trial" and "struggled at trial to suggest that the 'regulatory climate' had changed at FDA." Br. at 9, 19. GE introduced the FDA's Federal Register notice, but was barred from introducing any further evidence about the FDA's health-based change in treatment of HUAMs.

been a pretext designed to evade a clear agency policy of not granting 510(k) clearance for pre-term use. As the undisputed facts of this case make clear, by 1997 this was no longer true.

In discharging its crucial "gatekeeping" function, the FDA is empowered to change the classification of devices, and their eligibility for 510(k) treatment, based on new, and riskier, uses to which previously cleared devices are put. Such changes in the regulatory treatment of new devices pose no threat to the practice of medicine or "off-label" prescription practices. However, by ruling that GE could have legally filed a 510(k) application plainly calculated to evade the agency's new policy towards 510(k) clearance of HUAMs, the decision below significantly undermines the FDA's ability to implement such health-based policy changes in regulatory treatment. Respondent's attempt to convert health and safety regulation into a shell game by itself demonstrates the need for review of the ruling below.

4. Finally, respondent argues that this Court should ignore the conflict the decision below creates with another circuit and with the FDA because the opinion is too "cryptic" to serve as a "road map" for future regulatory violations of the type the Eighth Circuit blessed in this case. Br. at 9, 11. This Court, however, "'reviews judgments, not opinions.'" *Bowen* v. *American Hosp. Ass'n*, 476 U.S. 610, 625 n.11 (1986) (quoting *Chevron U.S.A. Inc.* v. *Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984)). It is the judgment below that conflicts with a holding of the Third Circuit as well as the expert views of the FDA, and this judgment should therefore be reviewed.

Of equal importance, the decision below can and will serve as both a blueprint for filing pretextual 510(k) notifications, and, perhaps even more importantly, as a defense to any persons who file such notifications. As *Buckman* itself makes clear, the filing of pretextual 510(k) notifications is regrettably more "commonplace," Br. at 9, than anyone would wish. See also *United States* v. *Barile*, 286 F.3d 749

(4th Cir. 2002) (reversing conviction for false 510(k) submission). And, as *Buckman* further demonstrates, the filing of such 510(k) submissions can cause serious injury to a great many people. Though devoid of reasoning, the Eighth Circuit's opinion makes clear that it involves the legality of 510(k) notifications. Accordingly, a manufacturer determined to evade meaningful review, or one accused of having filed a pretextual notification, will have no difficulty "familiari[zing] itself with the underlying facts" of this case, Br. at 11, which are a matter of public record. Such a manufacturer, moreover, will undoubtedly rely on the decision below as authority for why its conduct, like that contemplated under respondent's construction of the Transfer Agreement, did not "violate federal law." Pet. App. 3a. Because the decision below does in fact hold that it is not illegal for a manufacturer to claim an intended use that it has no intention of promoting, and for which no doctor will prescribe the device, the ultimate question is why this Court would turn a blind eye to such a disturbing holding. The integrity of the FDA's regulatory process and decisional consistency among the courts of appeals argue strongly in favor of further review. Compare *Norfolk & W. Ry.* v. *Ayers*, No. 01-963 (U.S. granted Apr. 1, 2002).

CONCLUSION

For the reasons stated above, the Court should grant the petition.

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November 12, 2002

APPENDIX

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
Rockville, MD 20857

[Received Mar. 7, 2001]

CERTIFIED MAIL
RETURN RECEIPT

Edward M. Basile, Esquire
King & Spalding
1730 Pennsylvania Avenue N.W.
Washington, D.C. 20006-4706

Re: Biomedical Systems Corp. v. GE Marquette Medical Systems, Inc.

Dear Mr. Basile:

This is in response to your February 20, 2001 letter to the United States Food and Drug Administration (FDA). Your letter requested the testimony of a FDA employee regarding the review process for reclassification petitions and specifically the GEMMS petition.

As your letter recognizes, a request for testimony from a FDA employee is governed by FDA regulation 21 C.F.R. § 20.1. This regulation prohibits FDA employees from testifying with respect to any information acquired in the discharge of his or her official duties except with the express authorization of the Commissioner of FDA or an employee designated by her to act on her behalf. As Director, Division of Compliance Policy, I have been delegated the authority by the Commissioner to review requests made under 21 C.F.R. § 20.1. *See* 21 C.F.R. § 5.20.

Section 20.1 allows FDA to allocate its limited resources in a manner that best effectuates the agency's public health mission. Section 20.1 provides that FDA may grant a request for testimony if it is determined that such testimony: (1) is in

the public interest, and (2) promotes the objectives of the Federal Food, Drug, and Cosmetic Act (FFDCA) and the agency. Both tests must be satisfied. Because of FDA's limited resources and the vast number of requests the agency receives for agency personnel to participate in litigation, it is not in the public interest, and it does not promote the objectives of the FFDCA, for agency personnel to routinely break from their public health mission to provide testimony in private lawsuits. FDA must deny requests that are unlikely to elicit relevant testimony, unduly burdensome, or otherwise inappropriate. Accordingly, the agency must carefully assess requests for testimony made pursuant to section 20.1. After considering your request, FDA has determined that your request is not in the public interest and does not promote the objectives of the FFDCA, and denies your request for testimony.

While FDA is not unsympathetic to these requests, it must decline to authorize its employees to provide testimony in their official capacity absent compelling circumstances. FDA's policy has been established to avoid the impression that FDA or one of its employees, is taking a partisan position in litigation, where, as here, the agency is not a party. FDA best serves the public not by providing witnesses in private litigation and other matters to which the FDA is not a party, but rather by enforcement of the FFDCA and related statutes. The proposed testimony would not promote the objectives of the FFDCA.

Any participation by FDA employees in disputes between private parties would require that agency employees divert a portion of their time and agency resources, away from primary FDA responsibilities. To allow preferential treatment to only one party in disputes to which FDA is not a party would jeopardize the agency's role as an impartial regulatory agency. If the agency appears to take sides in a private dispute, it would raise legitimate concerns as to the agency's

neutrality and send an inappropriate signal that the FDA may harbor bias toward certain interest. For this reason, the agency attempts to minimize the participation of its employees in controversial matters in which the agency is not a party.

In addition, your request does not differ significantly from many other request in which FDA has or has not taken an action with respect to any device, drug, biologic, food or cosmetic. FDA feels that 21 CFR § 860 explains the review process for reclassification petitions and that non-government experts are available to all parties in this proceeding, if necessary, to assist in interpreting the applicable statutes and regulations.

For the reasons stated above, I am unable to make the findings required by 21 C.F.R. § 20.1 and therefore your request for testimony is denied. If you have any questions, please contact Ms. Anne Smith at (301) 827-0422.

Sincerely yours,

/s/ David K. Haggard
DAVID K. HAGGARD
Director,
Divisions of Compliance Policy